Exhibit D

IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY, PENNSYLVANIA

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IN RE: PELVIC MESH/GYNECARE LITIGATION	:	MAY TERM, 2013
PATRICIA L. HAMMONS, Plaintiff, v. ETHICON, INC., et al., Defendants.	:	NO. 003913

- - -

DECEMBER 13, 2015

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Videotape deposition of JOYE LOWMAN, M.D., taken pursuant to notice, was held at the law offices of Drinker Biddle and Reath, LLP, One Logan Square, 18th and Cherry Streets, Suite 2000, Philadelphia, Pennsylvania 19103, commencing at 2:00 p.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter and Notary Public in and for the Commonwealth of Pennsylvania.

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- - -

- - -

INDEX

- - -

- - -

EXHIBITS

- - -

- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer
Page Line Page Line Page Line
None

Request for Production of Documents
Page Line Page Line Page Line
None

Stipulations
Page Line Page Line Page Line
7 1

Question Marked
Page Line Page Line Page Line
None

- - -

(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

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VIDEO TECHNICIAN: We're now on the record. My name is David Lane, videographer for Golkow Technologies. Today's date is December 13th, 2015. Our time is 2:17 p.m. This deposition is taking place in Philadelphia, Pennsylvania, in the matter of Patricia Hammons versus Ethicon, Inc., et al. Our deponent today is Dr. Joye Lowman, M.D.

Counsel will be noted on the stenographic record. Our court reporter today is Amanda Miller and will now swear in the witness.

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JOYE LOWMAN, M.D., after having been duly sworn, was examined and testified as follows:

- - -

VIDEO TECHNICIAN: Please begin.

- - -

EXAMINATION

- - -

BY MR. ISMAIL:

Q. Good afternoon, Dr. Lowman.

A. Hi.

Q. Could you please tell the jury your name and what you do for a living?

A. My name is Joy Lowman, and I'm a urodynamic gynecologist.

Q. Where do you practice, Dr. Lowman?

A. I practice at Kaiser in Atlanta, Georgia.

Q. Now, are we here today on a Sunday in the middle of the Hammons trial?

A. We are.

Q. And do you understand that the testimony you're giving today will be shown to the jury on Tuesday or Wednesday of this week?

A. I do.

Q. Doctor, did you want to have an opportunity to actually appear in court and testify to the jury in the Hammons case?

A. I did.

Q. In fact, are we here today just a few blocks from the courthouse?

A. Yes, we are.

Q. Why is it, Doctor, that you will be unable to appear in person on Tuesday or Wednesday of this week?

A. It's my understanding that the case has moved along much more quickly than was initially anticipated. I was scheduled to testify on Friday, and now it's anticipated that the case might end on Tuesday or Wednesday.

Unfortunately, I have surgical cases scheduled, as well as patient visits, office visits, scheduled and I don't want to compromise the care of those patients.

Q. Okay. So do I understand it, correctly, Dr. Lowman, that you have patients who have previously scheduled appointments for the first part of this week?

A. That's correct.

Q. Including patients who have surgeries scheduled that you are scheduled to perform for them?

A. Yes.

Q. In light of that, Doctor, did you feel it was necessary that you take care of and be present for your patients in Atlanta?

A. Absolutely.

Q. Nevertheless, Doctor, did you feel that it was important that you have an opportunity to give your opinions -- opinions and your findings to

the jury in the Hammons case?
MR. SLATER: Objection.
THE WITNESS: Yes, I do.
BY MR. ISMAIL:
Q. And is that why we're here today on a Sunday taking your testimony?
MR. SLATER: Objection.
THE WITNESS: Yes, it is.
BY MR. ISMAIL:
Q. Doctor, have we -- have we asked you to analyze certain topics and to discuss your findings with the jury?
A. You have.
Q. Have we asked you to discuss the disease of pelvic organ prolapse?
A. You have.
Q. And the treatment and the various options that are -- that have been used by surgeons to treat that condition?
A. Yes.
Q. Have we also asked you to analyze Patricia Hammons' medical history, particularly as it relates to

her use of PROLIFT® to treat pelvic organ prolapse?
A. Yes.
Q. Doctor, before we get to the substance of your opinions, I want the jury to have a better understanding of your professional education and training, okay?
A. Okay.
Q. And have you helped us put together some slides that will help explain some of the concepts that we're discussing with the jury?
A. I have.
Q. And we have up on the screen the first slide.
Does that describe your educational training and some of your professional training?
A. It does.
Q. It says that you went to college at Spelman College.
Where is that?
A. It's in Atlanta.

Q. Now, Doctor, did you begin, at an early point in your career, to have an interest in scientific research?
A. I did.
Q. Can you give us an example of that?
A. Yes, certainly. As a student at Spelman College, I was a member of the UMARC program, which stands for Undergraduate Minority Access to Research Careers. It was a scholarship program that provided money for us to be able to do basic science research.
Q. Did you continue your educational training to attend University of Pennsylvania here in Philadelphia?
A. I did.
Q. And what degree did you get from the University of Pennsylvania?
A. A Master's -- a medical degree.
Q. Did you continue, Doctor, on to get a Master's Degree at Columbia in New York City?

A. I did.
Q. And why did you pursue that career, or that additional training?
A. I wanted to perform clinical research and, unfortunately, the University of Pennsylvania doesn't have a clinical research track.
Q. And so what degree did you get from Columbia university?
A. An MPH, which is a Master's in Public Health.
Q. Doctor, did you -- withdrawn.
Can you explain for the jury what led you to your career path to end up as a urogynecologist and pelvic floor surgeon?
A. Yes. I've always had an interest in women's health, and I learned in residency that I loved surgery. And urogynecology, in my opinion, is the best merge of those two things.
Q. Did you do additional education and professional training in

Page 14

order to follow the career path you set out for yourself?
A. I did. I went to fellowship at Indiana University after my residency program.
Q. What was your residency program?
A. It was residency program in female -- I'm sorry, residency was general obstetrics and gynecology.
Q. And where did you do that?
A. At Abington.
Q. And what type of training did you get as part of your residency program in obstetrics and gynecology?
A. We trained in the evaluation and treatment of general obstetrics and gynecologic issues.
Q. And then you were starting to tell us that you did some additional training.
Was that through a fellowship?
A. That was through a

Page 15

fellowship.
Q. And what was your fellowship training?
A. It's -- my fellowship training was at Indiana University in female pelvic medicine and reconstructive surgery. Luckily, they are one of very few locations that also have a CITE training program, that stands for clinical investigator training enhancement program, sponsored by the NIH, to, basically, train clinical scientists.
Q. Is that additional training in clinical scientific methods and research, is that a part of every fellowship program that's out there?
A. It's not.
Q. Is that a unique aspect of your professional training that --
A. It is.
Q. -- that is -- did you find that to be beneficial in the opinions that we asked you to investigate in this

Page 16

case?
A. Very much so.
Q. How long was your fellowship at Indiana University?
A. Three years.
Q. And what types of training did you engage in while in fellowship there?
A. We evaluated complex female pelvic medicine and reconstructive surgery issues. It was a tertiary -- tertiary referral center, so anything dealing with matters of female pelvic floor dysfunction, which includes urinary incontinence, pelvic organ prolapse, fecal incontinence and pelvic pain.
Q. Are you board certified, Doctor?
A. I am.
Q. In what areas are you board certified?
A. General obstetrics and gynecology and in female pelvic medicine and reconstructive surgery.

Page 17

Q. So you have both board certifications?
A. I do.
Q. Doctor, have you conducted clinical research in your career?
A. I have.
Q. Can you describe for the members of the jury, just briefly, what that clinical research -- some examples of the work that you have done to contribute to clinical science?
A. Certainly. I have performed basic science, as I said, when I was an undergraduate. And then in terms of peer-reviewed publications, I've studied dyspareunia rates in particular after the PROLIFT®, as well as risk factors for mesh erosion after mesh augmented pelvic organ prolapse repair.
Q. So do I understand correctly, Doctor, that you have actually done clinical research in the areas of mesh implantation?
A. Yes, award-winning research.

Page 18

Q. Have you also done research that looked at the PROLIFT® in particular?
A. I have.
Q. Have you published research in the peer-reviewed medical literature?
A. I have.
Q. And does that include some of the research you've already described for us in polypropylene meshes and PROLIFT® in particular?
A. Yes.
Q. Doctor, have you, throughout your career, had experience surgically implanting mesh material?
A. I have.
Q. Polypropylene mesh?
A. Yes.
Q. Does that include experience implanting the PROLIFT®?
A. Yes.
Q. Can you give us -- first of all, Doctor, when did you first gain experience implanting the PROLIFT®

Page 19

through the procedure that was developed for that medical product?
A. In my fellowship.
Q. Was that at Indiana University that you've described for us already?
A. Yes.
Q. Do you have an estimate, Doctor, as to how many PROLIFT® procedures you have performed in your career?
A. Approximately 150.
Q. Do you also have experience, Doctor, implanting other types of mesh?
A. I do.
Q. Do you also have experience treating complications from mesh surgery?
A. I do.
Q. Do you have experience treating complications for non-mesh surgery used to treat pelvic organ prolapse?
A. I do.
Q. Doctor, what's your current

Page 20

position?
A. I'm currently the module lead for the urogynecology department at Kaiser.
Q. First of all, what is Kaiser?
A. Kaiser is a health management organization where a health plan or insurance company employs physicians to care for the patients that have that insurance.
Q. And do you have privileges at hospitals in Atlanta?
A. I do.
Q. Is that where you perform surgery and see patients?
A. Yes.
Q. What does it mean to be a module lead? Or, basically, describe what your duties are in the position you currently hold.
A. I, basically, oversee the department. The department is focused on evaluating and treating female pelvic

Page 21

floor dysfunction, and I oversee that process. I have one partner or colleague, another physician, that works with me, and we have three nurses that work with us.
Q. And what types of conditions do you treat in your clinical practice?
A. We treat anything that deals with the female pelvis, in particular as it relates to female pelvic floor dysfunction. So, again, urinary incontinence, pelvic organ prolapse, fecal incontinence, pelvic pain syndromes, and then lower urinary tract problems as well, like urethral diverticulum.
Q. Do you do surgeries?
A. I do.
Q. Do you have experience, Doctor, counseling women on their options on treating pelvic organ prolapse?
A. Yes.
Q. Is that an important part of your practice?

A. It is.
Q. Doctor, have you described for us your background, training, experience and research about pelvic organ prolapse, vaginal mesh, vaginal mesh procedures and pelvic surgery?
A. Yes.
MR. ISMAIL: At this time, I'd like to offer Dr. Lowman as an expert in urogynecology, including pelvic reconstructive surgery, vaginal mesh, vaginal mesh procedures and the PROLIFT® in particular.
MR. SLATER: We'll reserve.
BY MR. ISMAIL:
Q. Doctor, have you reached opinions in this case about the use of PROLIFT® to treat pelvic organ prolapse?
A. I have.
Q. Have you reached opinions in this case related to Mrs. Hammons' medical history, particularly as it relates to her pelvic floor disease and

her use of PROLIFT®?
A. I have.
Q. Doctor, will all the offers you offer today be to a reasonable degree of medical certainty?
A. They will.
Q. Before we get to the substance of the opinions, Doctor, I want the jury to understand the work that you did that led to the opinions that you will offer today, okay?
A. Okay.
Q. Did you review Mrs. Hammons' relevant medical records?
A. I did.
Q. Did you review the testimony of her and her treating physicians?
A. I did.
Q. Did you review the expert reports of plaintiff's experts, Drs. Weber, Zipper and Elliott?
A. I did.
Q. Did you review material that was -- withdrawn.

Did you review material such as the patient brochures, the surgical technique guide and the surgeon's monograph?
A. I did.
Q. Did you consider, as part of your work preparing your opinions in this case, the relevant medical literature on the issues you were asked to investigate?
A. Yes.
Q. Did you also, as part of forming your opinions, consider your experience, both as a clinical researcher and as a clinician treating women with this condition?
A. I did.
Q. Doctor, did you feel it was important, as part of your work, to review internal company e-mails?
A. No.
Q. Why not?
A. Because that's not what I base my clinical decisions on. I practice what is known as evidence-based

medicine, meaning that I use evidence in science, which is research studies, to base my clinical opinions on.
Q. Doctor, did you examine Mrs. Hammons in this case?
A. I didn't.
Q. Do you, nevertheless, feel that you are in a position to offer opinions about her case, particularly as it relates to her pelvic floor condition and her use of PROLIFT®?
A. I do.
Q. And why do you believe that?
A. Because I reviewed her medical records, I've read her testimony, as well as the testimony of her treating physicians, and I think that gives me a good gestalt of her condition.
Q. And when you say a "gestalt," does that mean an overall impression of the symptoms she reported, when she reported them and her disease state?
MR. SLATER: Objection.

THE WITNESS: That's correct.

BY MR. ISMAIL:

Q. Doctor, have you charged for the time that you have spent working on this case?

A. I have.

Q. And at what hourly rate?

A. $400 an hour.

Q. And if I -- do you have an estimate, Doctor, for the number of hours that you have spent on Mrs. Hammons' case in particular to arrive at the opinions you'll offer today?

A. I have been evaluating multiple cases, so it's not an exact estimate. But if I had to guess, I would guess around 100 hours.

Q. Let me rephrase my question and ask it this way -- new question.

Can you give me an estimate just about the amount of time that you spent on Mrs. Hammons' case, to date, that brought you to the point to offer

the opinions you're going to tell to the jury?

A. Approximately 100 hours.

Q. Doctor, I want to start with the condition that the jury has heard a lot about and that is pelvic organ prolapse, okay?

A. Okay.

Q. And at this point in the trial, the jury has heard a lot about pelvic organ prolapse. So I don't want to go over a description of the disease -- withdrawn.

Doctor, I want to start with discussing the public health impact of pelvic organ prolapse as you've seen it as a clinical researcher and as a clinician in this field, okay?

A. Okay.

Q. Do you have statistics that you use in your clinical research or as you counsel patients as to the prevalence of pelvic organ prolapse?

A. I do.

Q. Can you give the jury a sense of the -- how significant of a public health issue pelvic organ prolapse is?

A. Certainly. Pelvic organ prolapse is a very significant issue in this country and all over the world. It is the most common indication for hysterectomy in this country, and over 60 percent of women who have had children are affected.

Q. What are some of the risk factors that can lead to the development of pelvic organ prolapse?

A. The biggest risk factor is childbirth. That has been shown to increase the risk of prolapse in a dose-response relationship, which means that the more babies you've had, the greater your risk of developing prolapse.

Aging is the second biggest risk factor.

Chronic heavy lifting or straining, tobacco use, obesity; those

are the main ones.

Q. Doctor, do you see a range of symptoms in patients you treat who have pelvic organ prolapse?

A. I do.

Q. What are some of the symptoms you've seen, clinically, in patients who are presenting with this disease?

A. Most patients present with the chief complaint of feeling or sensing a vaginal bulge. Many patients will describe discomfort in particular with intercourse from pelvic organ prolapse. Some describe difficulty being able to urinate. Some describe difficulty being able to have bowel movements.

Those are probably the main ones.

MR. SLATER: I just want to say one thing for the record. I'm going to start to object every time you use the word "disease." I think it's mischaracterizes

Page 30

what's really happening.
MR. ISMAIL: I appreciate that.
BY MR. ISMAIL:
Q. Doctor, do you -- new question.
Doctor, do you believe that surgical intervention is appropriate for patients who have symptoms of pelvic organ prolapse?
A. Yes.
Q. Is that a belief that is supported, in your view, in the medical community?
A. Yes.
Q. Doctor, the jury has heard that watching and waiting is sometimes appropriate for a woman who is presenting with this condition.
Is that sometimes true?
A. Yes.
Q. What is to be expected if a patient does not receive any treatment for a prolapse with respect to the

Page 31

condition itself?
A. Most likely, it will progress.
Q. And so if a patient receives no treatment for a prolapse, what would be the expected course of that condition over time?
A. It most likely will worsen over time.
Q. Now, Doctor, the jury has heard this term "recurrence."
What does "recurrence" mean in the context of pelvic organ prolapse?
A. Recurrence refers to the fact that a patient may have had a surgical repair for prolapse and then re-present with prolapse subsequently.
Q. Is recurrence a problem that is faced with clinicians taking care of women with this condition?
A. Significantly, yes.
Q. Do you have any statistics that you use in your clinical research or as you counsel women as to the -- how

Page 32

common it is to have this problem of recurrence of a prolapse?
A. I do.
Q. And can you tell the jury some of that information?
A. Certainly. Over 50 percent of patients that have repair, in particular of the anterior compartment, which means the bladder, or a cystocele, will have recurrence of that prolapse without the use of mesh.
Q. Is there a particular patient type that is most vulnerable to a recurrence of a prolapse?
A. Yes.
Q. Can you tell the jury the characteristics of a patient who is most vulnerable for that?
A. Yes. So there are risk factors for the development of prolapse recurrence. Many of those risk factors overlap with development of prolapse in the first place.
So childbirth, obviously, is

Page 33

not going to be something that is going to develop subsequently. But aging, chronic heavy lifting, smoking, obesity and multicompartment prolapse; in addition to the grade of prolapse or the stage of prolapse are all -- all indicate that the patient may have an increased risk of recurrence.
Q. So one of the things that you said in your last answer was multicompartment prolapse. And I think that term came up before.
But can you remind us what you mean by multicompartment prolapse is?
A. Right. So the vagina is -- has a front vaginal wall, a back vaginal wall and then there's the top of the vagina. If there's a uterus present, it's at the top of the vagina. You can have prolapse in the anterior compartment, which is the front; prolapse in the posterior compartment, which is the back; or prolapse at the top of the vagina.

Page 34

Q. If a patient has multiple organ prolapse but receives treatment for only one of those prolapse conditions, what is to be expected about the compartment that did not receive treatment?
A. It most likely will progress.
Q. Now, Doctor, I want to talk about the surgical options for prolapse, particularly as it relates to 2009, which is the time frame that Mrs. Hammons was receiving her treatment for the condition, okay?
A. Okay.
Q. Were you a practicing surgeon in 2009?
A. I was.
Q. And was part of your practice treating women like Mrs. Hammons who had pelvic organ prolapse?
A. Yes.
Q. Doctor, what are -- are there factors that influence what surgery

Page 35

a surgeon may recommend to a patient who is experiencing prolapse?
A. Yes.
Q. And can you tell us what those are?
A. Yes. So there are patient factors, there are physician factors, and then there are also factors that affect sort of, you know, what devices you have at your disposal.
So the patient may have risk factors for recurrence that allow you -- that encourage you to use a more aggressive therapy. The patient may also have risk factors for morbidity, which means risk -- morbidity means sort of negative outcomes after surgery. You have to take that into account as well.
The surgeon also has to consider what they're able to do, what they've been trained to do. So while I have been trained in one of the best training programs in the country, I have the complete armamentarium to treat

Page 36

patients with pelvic organ prolapse. But many of my GYN colleagues, many of my urogyn colleagues are not trained to do abdominal sacrocolpopexy, for example, so that particular treatment is not an option for every patient.
Q. So have we put on the screen, Doctor, a graph that you helped us to put together to explain this concept?
A. Yes.
Q. So when you talk about patient factors, are those factors specific to the patient who is experiencing the condition?
A. Yes.
Q. And what were some of those factors again?
A. The patient's medical condition. We call it their comorbidities, meaning, are they diabetic? Are they hypertensive? Do they -- are they obese? Things that put them at risk for surgical complications.

Page 37

We have to consider that.
The degree of their prolapse. How bad is their prolapse? How aggressive do we think we have to be?
And then in terms of surgeon factors, it's what I described.
Q. So in terms of patient factors, can the type of conditions the patient has and the type of prolapse the patient has dictate that one option may be more appropriate an another?
A. Yes.
Q. And then you described surgeon factors.
Does that, basically, referred to what types of surgeries the surgeon is comfortable doing?
A. Right.
Q. And then product factors. What are you referring to there?
A. What are your options in terms of products. So what products are available? There -- you know, you may --

Page 38

want to do a vaginal procedure for a patient but if you don't have a vaginal product that works well, that's not going to be an option for you. So it talks about the fact of -- what I mean by that is, you know, what products are available and how well they work.

Q. And do some of the surgeries that you've described use polypropylene mesh?

A. Yes.

Q. Is abdominal sacrocolpopexy an example of a surgery that uses polypropylene mesh?

A. Yes.

Q. Is the PROLIFT® an example of transvaginal mesh?

A. It is.

Q. Are there other types of surgeries that rely on the patient's own native tissues?

A. Yes.

Q. Are there surgeries that use different material that -- different

Page 39

biologic material that can be used to repair a prolapse?

A. Yes.

Q. Can you give us an example of those biologic materials?

A. Yes. So there are grafts that we have available to repair pelvic organ prolapse. Most of them are taken from other animals, those are called xenografts; they come from either pig, which is called porcine graft, or cow, which is called a bovine graft.

Q. Let me stop you there for a minute, Doctor.

So you've described that there's polypropylene mesh that can be implanted transvaginally, correct?

A. Right.

Q. And you described native tissue repair surgery, correct?

A. Correct.

Q. And you've described a different type of surgical repair using biologic tissue, for example, from an

Page 40

animal?

A. Right.

Q. Did Mrs. Hammons have all three of those types of surgeries over time?

A. She did.

Q. Now, Doctor, do you believe that all surgical procedures carry potential risks along with hope for benefits?

A. Yes.

Q. Is that true in the field of pelvic reconstructive surgery?

A. Yes.

Q. What are some of the potential complications or drawbacks of a surgical repair of a pelvic organ prolapse?

A. So some of the potential complications with repair of pelvic organ prolapse are general to all surgeries. So risks of bleeding, risk of infection, risk of damage to the organs that you're working around.

Page 41

There are other potential risks that are inherent to prolapse surgeries, and mostly postop complications, which is failure to cure or recurrence of prolapse. And if you're using mesh augmentation, there's the risk of mesh erosion or a mesh complication.

Q. Are there -- what are the benefits that a surgeon is trying to accomplish when recommending a surgery for pelvic organ prolapse?

A. The goal of surgery for pelvic organ prolapse is to restore normal anatomy and function.

Q. Now, let's talk about the PROLIFT® in particular.

You told the jury already that your experience included 150 surgeries implanting the PROLIFT®; is that correct?

A. That's correct.

Q. When you recommended a PROLIFT® for your patients, why did you do so?

A. Because I feel that it's a safe and effective procedure.
Q. When you recommended a PROLIFT® for your patients, what goal were you trying to accomplish for your patient?
A. I wanted to restore normal anatomy and function.
Q. And when you recommended the PROLIFT®, did you believe that it was a safe and effective procedure for your patients?
A. I do. I did.
Q. And in terms of the success of treating a pelvic organ prolapse, has the PROLIFT® been shown to be effective in treating the condition?
A. Yes.
Q. Now, Doctor, you already told the jury about the term "evidence-based medicine."
Do you recall saying that earlier in your testimony?
A. I do.

Q. Explain to the jury what evidence-based medicine is.
A. Evidence-based medicine is using science to make decisions about how best to impart clinical care.
Q. What is the role of evidence-based medicine in assessing the benefits and risks of surgical options?
A. The role of evidence-based medicine is to guide us, to guide physicians in trying to make decisions about what procedures, medications, et cetera, we're going to offer to our patients.
So there's a wealth of literature in our community about the success rates, failure rates, complication rates of various treatment options, whether they be surgical or nonsurgical.
We have to have some guide in trying to decide what -- which evidence is strongest.
Q. Is all scientific evidence

treated equally in evidence-based medicine?
A. It should not be. That's not -- that's what evidence-based medicine is, not -- figuring out what evidence is strongest, meaning which evidence is most reliable.
Q. So is -- some types of scientific evidence more reliable than others?
A. Yes.
Q. Is there an accepted ranking of reliability when it comes to reviewing scientific evidence when you're trying to answer important medical questions?
A. Yes.
Q. Doctor, we have on the screen here a pyramid.
Can you just give the jury an overview of what we're looking at here?
A. Yes. So this pyramid depicts what we refer to as levels of evidence. That means that evidence is

graded in a hierarchal fashion so that at the top of the grading scale are the types of studies that provide us the most reliable evidence, and at the bottom of the scale, or at the bottom of the pyramid, are the types of studies that give us the least reliable evidence.
Q. So if we were looking at this pyramid here, under the principles that you've described, as we go towards the top, are those the more reliable forms of evidence?
A. Yes.
Q. And as we go towards the bottom, are those the less reliable forms of evidence?
A. That's correct.
Q. So, for example, you have at the top something referred to as systematic reviews and meta-analysis?
A. Right.
Q. Can you just, in a few sentences, tell us what that means?
A. Yes. So systematic reviews

Page 46

and meta-analyses compile the data of smaller studies and evaluate it in total. And it gives you a stronger sense of how the disease process or the intervention is experienced in the population.

Q. Why is that type of scientific evidence more reliable than, say, individual case reports or individual anecdotal experience of physicians?

A. It minimizes bias.

Q. When you were addressing the issues that we asked you to investigate in this case, did you use evidence-based medicine in your analysis?

A. I did.

Q. Did you review the opinions of Drs. Elliott, Weber and Zipper?

A. I did.

Q. Did you see any indication that any of them used evidence-based medicine in the opinions they offered the jury?

A. No, they didn't.

Page 47

Q. Doctor, I want to now turn to some of the specific opinions you have on the PROLIFT® product, okay?

A. Okay.

Q. The first question I want to address is the -- what does the scientific evidence show on the effectiveness of PROLIFT® to treat pelvic organ prolapse, okay?

A. Okay.

Q. Doctor, did you form an opinion, as part of your work in this case, as to the effectiveness of the PROLIFT® to treat pelvic organ prolapse?

A. I did.

Q. What did you consider to form your opinions in this case?

A. I considered the scientific evidence and my clinical experience.

Q. What is the opinion -- what is your opinion, Doctor, as to what that evidence shows about the effectiveness of the PROLIFT® to treat prolapse?

A. It's very effective.

Page 48

Q. You indicated, Doctor, that you, as part of your work in this case, followed the pyramid of reliability, if I can call it that?

A. Yes.

Q. Did you consider the highest quality data in answering the question that you've presented to the jury today?

A. I did.

Q. Now, what I have up on the screen, Doctor, is this an example of some of the data that you considered in this case?

A. This is.

Q. Now, let's sort of orient the jury to what we're looking at here. It's called a Cochrane review?

A. That's correct.

Q. What is a Cochrane review?

A. So when we were looking at the levels of evidence, at the very top of the pyramid is a meta-analysis, or a summary of well designed randomized

Page 49

control trials.

The Cochrane review of 2013 is exactly that. It's an evaluation of all of the randomized controlled trials, up until that date, of pelvic organ prolapse.

Q. And this particular analysis here is looking at the success of native tissue versus mesh repair?

A. That's correct.

Q. And so does this look at multiple polypropylene mesh products for treatment of a bladder prolapse?

A. It does.

Q. And there's some medical terminology in the middle there, anterior colporrhaphy?

A. Colporrhaphy.

Q. Is that a native tissue surgery?

A. That's a native tissue surgery.

Q. And it says, versus, and then it describes these transobturator

Page 50

polypropylene mesh kits; is that correct?
A. That's correct.
Q. And so would PROLIFT® be an example of one of those mesh kits?
A. Yes.
Q. So let's look at what the data is that you considered.
So can you tell the jury, sort of orient us as to what we're looking at here and how that was significant, if at all, to the opinions you offer to the jury?
A. Yes. So what this depicts is that the analysis revealed that the risk ratio of success is much higher with mesh augmentation than it is if you perform the procedure using native tissue.
So a risk ratio is how much more likely is the outcome, the outcome being success. So a risk ratio of 3.83 shows you that it's almost four times more likely to achieve success with mesh than without mesh. And this study

Page 51

included 56 randomized control trials and over 6,000 patients.
Q. When you say -- withdrawn.
The jury has heard about this concept of statistical significance through another witness.
Was this finding that you're reporting here or that you relied upon statistically significant?
A. Overwhelmingly, yes.
Q. And so the jury has heard about different ways that researchers can measure success with a surgical repair of prolapse.
A. Okay.
Q. We've heard about anatomic measures and symptomatic measures.
A. Right.
Q. Are you familiar with those concepts as well?
A. I am.
Q. Can you remind us, Doctor, what is an anatomical measure of success following surgery?

Page 52

A. So an anatomical measure of success is when I do my physical examination of the patient, do they still have prolapse or not?
Now, you can quantify that with the pelvic organ prolapse quantification exam or with the BARD system, but it basically is that.
Subjective evaluation is, does the patient feel that they're improved?
Q. And the success measure that you're reporting here, the four times greater success with mesh compared to native tissue, what success measure are you using with this data?
A. Anatomic success.
Q. Do you believe that is an appropriate way to assess the success of surgeries?
A. I do.
Q. And why is that?
A. Because the goal of surgery is to restore normal anatomy and

Page 53

function. The only way to objectively evaluate whether or not you restore normal anatomy is with the POP-Q or the BARD halfway system.
Q. The data that you relied upon to arrive at your opinion about the effectiveness of PROLIFT®, the ones that we're showing the jury now on the screen, do those -- does that data actually include studies on the PROLIFT®?
A. Yes, it does.
Q. You mentioned that there was an alternative measure of success, the symptomatic outcomes; is that correct?
A. That's correct.
Q. Has the PROLIFT® been studied in clinical trials to assess whether the PROLIFT® improved symptomatic outcomes as well?
A. It does -- or it has been.
Q. And can you tell the jury what the results of that research is?
A. It improves symptomatic success as well.

Page 54

Q. So, Doctor, based on the information that you have reviewed with the jury -- by the way, the studies that you've described, do you find them reliable?
A. Yes.
Q. And do you find them authoritative?
A. Absolutely.
Q. Based on the information you reviewed with the jury and your own clinical experience, do you have an opinion as to whether or not the PROLIFT® is effective in improving patient's quality of life?
A. It is.
Q. And as to the question of whether a PROLIFT®, how it compares to native tissue surgery, do you have an opinion as to how effective PROLIFT® is in treating the prolapse itself compared to a native tissue surgery?
A. It's significantly more effective.

Page 55

Q. And is that for the reasons you've discussed with the jury already today?
A. Yes.
Q. Have there been data that have examined the issue of dyspareunia following surgery for pelvic organ prolapse?
A. There has been.
Q. Now, Doctor, dyspareunia, first of all, remind everyone, dyspareunia, does that mean painful sexual intercourse?
A. It does.
Q. Is dyspareunia a potential complication of any surgery to treat pelvic organ prolapse?
A. It is.
Q. And why is that?
A. One reason is that the incidence of dyspareunia in the patient population that we're treating is high to begin with, before they ever have surgery.

Page 56

Secondly, we're operating in the vaginal compartment, which is the female sexual organ. Whenever you make an incision on any part of the body, there's a risk that the patient may develop pain in the area of that incision.
Q. So is that true with surgeries that use mesh?
A. Yes, it is.
Q. Is that true with surgeries that don't use mesh?
A. Yes, it is.
Q. Have there been studies that have compared the risk of dyspareunia with the PROLIFT® to procedures that don't use mesh?
A. There are.
Q. Did you consider that research in forming your opinions that you're going to offer to the jury in this case?
A. Yes.
Q. And as part of your work in

Page 57

this case, Doctor, have you formed an opinion as to how PROLIFT® compares to, say, native tissue surgery on this question of the risk of dyspareunia?
A. I have.
Q. And what is your opinion?
A. They're no different.
Q. What do you base that opinion on?
A. The study that we just talked about, the Cochrane review, is the strongest level of evidence; but there are several studies that show that.
Q. And so, again, as to the methodology you followed in this case, did you use the principles of evidence-based medicine that you've described for the jury already?
A. I have.
Q. Okay. Doctor, do we have up on the screen some of the evidence you considered on this question of the risk of dyspareunia with PROLIFT® compared to native tissue surgery?

Page 58

A. It does.
Q. You mentioned, for example, the Cochrane review.
Is that this study that I have highlighted here on the screen?
A. It is.
Q. Now, what does the data show, Doctor, in terms of the risk of developing painful sexual intercourse following a PROLIFT® compared to native tissue surgery?
A. That it's not significantly different.
Q. Okay. So let's -- by the way, all these studies that are referenced here, did you review them?
A. I did.
Q. Do you find them reliable?
A. I do. They are randomized control trials.
Q. Did you find them authoritative on to this question, as to this question?
A. Yes, yes.

Page 59

Q. Now, there's this term here we have up at the top, de novo dyspareunia.
A. Yes.
Q. Can you tell us what that means?
A. That means new onset dyspareunia, meaning that they didn't have pain or they didn't have dyspareunia before surgery.
MR. SLATER: Do you have copies of what you're using that you can give to us? All the different slides you've used so far.
MR. ISMAIL: Yes. My apologies. One moment, Doctor.
BY MR. ISMAIL:
Q. Now, Doctor, why is it important to consider new onset dyspareunia when doing studies on this patient population?
A. Because you're trying to assess whether or not the procedure

Page 60

itself caused the dyspareunia.
Q. You mentioned that one of the things that's part of this patient population is that there's just a high incidence in general of dyspareunia?
A. That's correct.
Q. What do you mean by that?
A. What I mean is that the patient population that we are treating consists of women that have female pelvic floor dysfunction. And many of those women are in the menopausal age group. That age group is a high-risk group or a high-incidence group, high prevalence is the appropriate word, in terms of dyspareunia. There's a lot of dyspareunia in that group of patients.
Q. Are there a lot of different factors that can lead a woman to have problems with painful sexual activity?
A. Yes.
Q. Are those conditions common in the patient population who also have pelvic organ prolapse?

Page 61

A. Yes.
Q. Doctor, based on the scientific data that you have reviewed and have presented to the jury, do you have an opinion as to how PROLIFT® compares to native tissue surgery as to the risk of developing dyspareunia following the surgery?
A. They are not significantly different.
Q. And is that reflected here in this chart that we're showing to the jury now?
A. Yes.
Q. And so we have on this column, do we put in the various percentages of de novo dyspareunia or at least postoperative dyspareunia with the various studies that are reflected here?
A. Yes.
Q. And there may be some numerical differences between the two groups?
A. Yes.

Page 62

Q. Do researchers have a way to assess whether those differences are likely real or just potentially due to chance?
A. Yes.
Q. And what is, just in general, that concept in clinical research called?
A. It's called power.
Q. And do you use those concepts to determine whether a difference is statistically significant?
A. Yes.
Q. And have you marked here on this chart whether the observations in any of these studies show any significant difference between PROLIFT® mesh and native tissue surgery?
A. There's -- yes, there's no difference.
Q. Now, Doctor, have you, yourself, done research in this particular area?
A. I have.

Page 63

Q. And can you generally describe, in a few sentences, the study that you did that contributed to this research?
A. I performed a study, when I was a fellow, evaluating the rate of de novo dyspareunia after PROLIFT® procedures.
One of the main goals was to come up with an incidence for de novo dyspareunia, but also we really wanted to evaluate, in more detail, the type of dyspareunia that was being experienced by this group of patients, how mild it was, whether it was severe, whether it was moderate, where they were experiencing the dyspareunia.
And then I also wanted to know, is the dyspareunia so significant that you would not have had this procedure done.
Q. Did you publish your data?
A. I did.
Q. In the peer-reviewed

Page 64

literature?
A. Yes, I did.
Q. Did you also present your data at a medical conference?
A. I did.
Q. Dr. Weber was here last week, I believe, and told the jury that your study showed a rate of dyspareunia with the PROLIFT® in excess of 30 percent.
Is Dr. Weber correct?
A. She's not.
Q. Why not?
A. Because the -- my study showed a rate of de novo dyspareunia of 16.7 percent.
Q. You said that you also, as part of your study, examined the question of whether patients ultimately were satisfied with their procedure even if they developed dyspareunia?
A. That's correct.
Q. And what did your research show as to that question?

Page 65

A. It showed that they were very satisfied, as indexed by the answer to the question, would you have this procedure performed again, over 85 percent of the patients with de novo dyspareunia answered yes. Over 90 -- I think it was 96 or 97 percent of the group overall answered yes.
Q. And what does that tell you, Doctor, as a clinical researcher, as to the risks and benefits of a PROLIFT® procedure to treat a woman's pelvic organ prolapse?
A. The risks are overall low and the benefits are overall high.
Q. Doctor, based on the high-quality scientific data you reviewed, your personal experience implanting a PROLIFT®, do you have an opinion as to whether the PROLIFT® was a safe and effective option to treat Mrs. Hammons' PROLIFT® -- prolapse in May of 2009?
A. I do.

Page 66

Q. And can you tell the members of the jury what your opinion is?
A. My opinion is that the PROLIFT® was a safe and effective procedure to offer Mrs. Hammons.
Q. And do you -- new question.
Can you tell the members of the jury what you are relying upon for that opinion?
A. I am relying on the highest levels of evidence and my clinical experience.
Q. In your opinion, Doctor, did the benefits of the PROLIFT® procedure outweigh its potential risks to a patient such as Mrs. Hammons?
A. Yes.
Q. In your opinion, was the PROLIFT® a defective product in any way?
A. No.
Q. Doctor, I want to switch gears here.
MR. SLATER: Counsel, just for the record, we object to this

Page 67

document, since there's absolutely no evidence in the record that Dr. Baker saw it. Moreover, it was not even available to be given to him during his training because it's approved in 2007. He was trained in 2006. So without any testimony -- any evidence whatsoever that he would have seen it, we believe it to be irrelevant and potentially confusing and misleading.
BY MR. ISMAIL:
Q. Doctor, we've handed you Exhibit -- Defense Exhibit-24240.
Are you familiar with this document?
A. I am.
Q. Can you tell us what it is?
A. It's the surgeon's resource monograph dealing with the PROLIFT®.
Q. And just in general terms, what is a surgeon's resource monograph?
A. It's basically a resource

Page 68

for physicians that allows them to review information that Gynecare provides to them about this procedure.
Q. Can these documents, these resource monographs, an example of which looking at now, be a source of information for physicians about the risks and benefits of a product?
A. Yes.
Q. Does the resource monograph here for the PROLIFT® include information about the surgical technique?
A. It does.
Q. Does it include information about the potential risks and complications of the procedure?
A. It does.
Q. Do all surgical products have a monograph like the one we're showing right now?
A. Not that I'm aware of.
Q. Is a device manufacturer the only source of information for surgeons who are using that medical device?

Page 69

A. No.
Q. What else does a surgeon, in your experience, look to, to understand the risks and benefits of a surgical procedure they are performing?
A. First of all, we should be evaluating the medical literature primarily; our clinical experience; our training.
We often go to what's called continuing medical education courses. So when we go to national meetings, there are lectures and such that teach us about products like these.
Q. Doctor, I'm going to ask that you turn to Page 7 of the monograph. Actually, it's Page 6 of the monograph.
Let me know when you're there.
A. I'm there.
Q. There's a section called, Concomitant Procedures.
Do you see where I am?
A. I do.

Page 70

Q. And I want to review some of this information that is reflected here.
A. Okay.
Q. First of all, the word "concomitant," what does that mean?
A. That means at the same time.
Q. And then let's review this first sentence.
Can you read to the jury what I'm highlighting on the screen now?
A. It is unclear what percentage of Gynecare PROLIFT® system procedures involve both compartments, but it is common to utilize Gynecare PROLIFT® system in the most at-risk compartment and treat the other side with a traditional repair or leave it untreated in the absence of prolapse.
Q. So there's a lot there. Let's go over it so we can discuss to the jury what's being communicated here.
A. Okay.
Q. So when the surgeon's monograph talks about there are -- that

Page 71

it's common to use the PROLIFT® system in the most at-risk compartment --
MR. SLATER: By the way, we have an objection to this document also as a hearsay document.
MR. ISMAIL: Start over.
BY MR. ISMAIL:
Q. When the surgeon's monograph communicates that the PROLIFT® system is most commonly used at the most at-risk compartment, what does that mean?
A. It means that when we are trying to decide how to treat each compartment, we're considering the prognosis, if you will. Prognosis means how likely is this compartment to fail.
So if a patient is presenting with an advanced stage of prolapse in one compartment and a minor stage of prolapse in the other compartment, those compartments are at risks that are differential. So we often will use more aggressive treatment to treat the most at-risk compartment and

Page 72

less aggressive a treatment in the lesser compartment.
Q. So -- and, again, in your answer here when you're saying -- using the word "compartment," are you describing, basically, different organ prolapse?
A. I'm describing the front vaginal wall versus the back vaginal wall versus the top of the vagina.
Q. And so when the monograph describes using a PROLIFT® in the most at-risk compartment and the surgeon can decide whether to treat any other prolapse the patient is presenting with a different type of repair or leave it untreated, does the monograph go on to describe some things that the surgeon should consider in making that decision?
A. It does.
Q. And is that provided in the very next sentence?
A. It is.
Q. So does the next sentence

Page 73

read, The advantage of this approach is to reduce the mesh load and to avoid over treatment?
A. It does.
Q. And then does it go on to say, The disadvantage is that it's estimated that 30 percent of all recurrences are actually uncovering of occult defects in the side untreated with mesh may be prone to failure as it takes a greater percentage of the Valsalva forces over time?
A. That's correct.
Q. There's a lot of new terms in there, so let's take it one at a time.
A. Okay.
Q. First of all, Valsalva forces.
What are those?
A. Valsalva is the act of bearing down. So we consider Valsalva to be, you know, pushing down like in the process of having a bowel movement, coughing. That's what that describes.

Page 74

Q. And then the monograph describes uncovering of occult defects.
What does that mean?
A. That means that there are defects that relate to pelvic floor dysfunction that may not have manifested at the time that you're evaluating and treating the patient.
So it's describing the fact that whatever has led the patient to have the prolapse that is large is also affecting the other compartments and may eventually lead to those compartments developing prolapse as well.
Q. So, overall, what is this information telling surgeons to consider when faced with a patient who has prolapse of multiple organs?
A. What they are saying is that you should consider treating less aggressively compartments that are less severely affected by prolapse. However, you have to also recognize that there's a risk of developing prolapse in those

Page 75

compartments if you leave them untreated.
Q. In that example that you provided there, is the PROLIFT® causing a prolapse in the untreated compartment?
A. No. That whole scenario would hold true regardless of whether or not you're treating the anterior compartment with or without mesh.
Q. What do you mean by that?
A. What I mean is that this -- what they're describing is the scenario regardless of whether or not you use mesh to treat -- in treatment or not.
So if I were planning on taking a patient to the operating room for native tissue repair and I opt to support her apex, or the top of the vagina, because that is the most prominent prolapse and to not address her front vaginal wall or her back vaginal wall, she's at risk for failure in her front vaginal wall and back vaginal wall because I opted not to treat them.
Q. And if that patient

Page 76

subsequently developed a prolapse of the front or back vaginal wall, did the native tissue surgery cause that prolapse?
A. No.
Q. In the example of a PROLIFT®, where the surgeon opts to treat only one part or one compartment and the patient develops a prolapse in another compartment, did the prolapse -- PROLIFT® cause the subsequent prolapse?
A. No.
Q. Doctor, you indicated that the surgeon's monograph provides some information on potential complications with the PROLIFT® procedure; is that correct?
A. Yes.
Q. So if we go forward to Page 7, is there a list of potential complications that is reflected here?
A. Yes.
Q. And does -- in the pages that follow, the surgeon's monograph

Page 77

provide more information on various of these topics?
A. Yes.
Q. Let's go ahead and show some of that for the ladies and gentlemen of the jury.
On the next page, is there a section that's entitled, Mesh Complications, Erosion, Exposure and Extrusion?
A. That's correct.
Q. Now, the jury has heard these terms in the past.
Are erosion, exposure and extrusion known complications of any mesh procedure?
MR. SLATER: Objection.
THE WITNESS: Yes.
BY MR. ISMAIL:
Q. What is mesh erosion?
A. Well, that definition has changed over time. When we first started discussing mesh complications, mesh erosion meant an exposure of the mesh in

Page 78

the vagina.
There has been some -- we've had debate in our community about how to define mesh complications. And now mesh erosion is often considered a migration of the mesh into a visceral organ.
Q. Such as the bladder?
A. Such as the bladder.
Q. And then an exposure and an extrusion?
A. An exposure now means what we used to call mesh erosion, which is an exposure of the mesh in the vagina.
And extrusion is a large exposure of the mesh in the vagina or a wound dehiscence.
Q. Do you have -- when you say "wound dehiscence," what does that mean?
A. That means that it appears that the incision failed to heal.
Q. Do you have an opinion, Doctor, as to whether the potential complications of mesh erosion, exposure, and extrusion are well known in the

Page 79

surgical community that operates on a pelvic organ prolapse?
A. They are very well known.
Q. And what do you base that on?
A. Our meetings, the literature. I mean, it's constantly discussed.
Q. Have you reviewed this information here in this page and the page that follows that Ethicon provided on these potential complications of mesh erosion, exposure, and extrusion?
A. Yes.
Q. And have you formed an opinion, Doctor, as to whether this information adequately describes these potential complications for surgeons using the product?
A. Yes.
Q. And what is your opinion?
A. I feel that it was comprehensive and representative.
Q. Going forward, Doctor, there

Page 80

is a section on dyspareunia and vaginal pain.
And if we actually go forward, that information continues on the next page; is that correct?
A. Yes.
Q. Now, do you have an opinion, Doctor, as to whether, even without the surgeon's monograph, whether the risk of painful sexual intercourse following a PROLIFT® procedure was well known in the community of surgeons who are doing pelvic reconstructive surgery?
A. It's well known.
Q. And what do you base that on?
A. I base that on my clinical experience. The literature constantly talks about -- or consistently talks about that being a potential risk with any surgery.
Q. Have you reviewed the information that Ethicon included in this monograph as to the potential

Page 81

complication of dyspareunia and vaginal pain?
MR. SLATER: I just want to make it clear, we renew the objection to the testimony of a document that Dr. Baker never saw, as far as the record exists, and generalized testimony about what other doctors may or may not have seen or known where, as what's relevant, most relevant here is whether Dr. Baker knew these things.
MR. ISMAIL: I'll re-ask my question.
THE WITNESS: Okay.
BY MR. ISMAIL:
Q. Have you reviewed the information that Ethicon included in this monograph as to the potential complication of dyspareunia and vaginal pain?
A. Yes.
Q. Have you formed an opinion

Page 82

as to whether this information adequately describes this potential complication of dyspareunia to surgeons using the PROLIFT®?
A. Yes, I did.
Q. And what is your opinion?
A. My opinion is that it's comprehensive and reliable.
Q. Is the information that Ethicon provided here consistent with how the potential complication of dyspareunia is described in the medical literature?
A. It is.
Q. So, Doctor, we've just walked through one example of the type of information that was available to surgeons in this time frame about the potential complications of the PROLIFT®; is that correct?
A. Yes.
Q. And I think you indicated that pelvic floor surgeons have access to other information --
A. Certainly.

Page 83

Q. -- that can provide data or descriptions of potential complications?
A. Yes.
Q. So when we consider the group of physicians who would be implanting the PROLIFT®, do you have an opinion, Doctor, as to whether the information provided by Ethicon overall adequately described the potential complications of the procedure?
A. It did.
Q. And just for the benefit of the record, I think I asked you whether you had an opinion as to whether or not the information provided by Ethicon overall adequately described the potential complications of the procedure.
Do you have an opinion on that issue?
A. Yes, I do.
Q. And can you tell the members of the jury what your opinion is?
A. My opinion is that Ethicon's educational materials adequately

Page 84

describes the potential risks associated with the PROLIFT®.
Q. Dr. Lowman, I now want to turn to Mrs. Hammons in particular, okay?
MR. SLATER: One second. I just want to make one thing clear. Form objections you wanted me to make. Other objections are preserved?
MR. ISMAIL: Such as?
MR. SLATER: Other objections, relevancy, whether or not it fits the case.
MR. ISMAIL: You have been.
MR. SLATER: We have been, right.
MR. ISMAIL: So you have been making them.
MR. SLATER: Well, I've made a few because I wanted you to have the benefit of knowing what I was going to object to on other things. I have other objections. For example, we don't think Dr.

Page 85

Lowman is qualified to give warnings opinions, and we believe her opinions are not opinions based on deposition testimony.
MR. ISMAIL: I appreciate that.
MR. SLATER: Also, just for the record, her answers are overbroad and ambiguous as to what she's actually talking about. You have her generalizing about whether they gave information. We don't think that's adequate, and we think that should be precluded at trial.
MR. ISMAIL: Are you ready to proceed, Doctor?
THE WITNESS: Yes.
BY MR. ISMAIL:
Q. So to address Mr. Slater's concerns, let's return to the topic we were just discussing.
A. Okay.
Q. Dr. Lowman, have you been

Page 86

part of the surgical community that has treated women with pelvic organ prolapse for over a decade?
A. I have.
Q. Have you attended scientific conferences with other surgeons who treat women with pelvic organ prolapse?
A. I have.
Q. Have you gone to scientific meetings and discussed with colleagues the surgical options to treat pelvic organ prolapse?
A. I have.
Q. Have you engaged in clinical research that has caused you to interact with other surgeons on the surgical options to treat prolapse?
A. Yes.
Q. Have you reviewed the scientific literature that discusses the information that's out there in the community on the risks and benefits of surgeries to treat prolapse?
A. Yes.

Page 87

Q. Through your exposure that you've just described for the jury, do you have an understanding of the type of information that is available to surgeons overall to inform them about the risks and benefits of surgical procedures?
A. Yes.
Q. Have you considered the information put out by Ethicon at various points in time about the PROLIFT® device in particular?
A. I have.
Q. Does that include the surgeon's monograph that we looked at?
A. Yes.
Q. Did you look at the instructions for use?
A. Yes.
Q. Did you look at the patient brochure?
A. Yes.
Q. Based on your clinical experience and your activity as a clinician and researcher in this field,

Page 88

do you have a basis, Doctor, to testify to what the information that was available to surgeons overall on the risks and benefits of the PROLIFT®?
MR. SLATER: Same objection as before. And form of the question.
THE WITNESS: You're asking me about my expertise and am I qualified to give opinions in this case?
BY MR. ISMAIL:
Q. Let me rephrase.
Doctor, based on the activities you've described for the members of the jury that you've engaged in, both as a clinical researcher and surgeon, have you formed opinions as to the type of information that was available to surgeons who were operating on women with pelvic organ prolapse?
A. Yes.
Q. Did you, as part of your work in this case, consider whether the

Page 89

information put forth by Ethicon, given the target audience of physicians who would be using this product, whether that information adequately described the potential complications of the procedure?
MR. SLATER: Same objection.
THE WITNESS: Yes.
BY MR. ISMAIL:
Q. What -- and can you tell the members of the jury what your opinion is on that issue?
A. My opinion is that Ethicon provided adequate educational materials in discussing the potential risks and benefits of their -- of the PROLIFT®.
Q. Now, let's turn to Mrs. Hammons in particular, okay?
A. Okay.
Q. Did you review Mrs. Hammons' medical records to arrive at your opinions in this case?
A. I did.
Q. And did you consider the sworn testimony of both her and her

Page 90

doctors?
A. Yes.
Q. Now, I want to start with this question of whether the PROLIFT® was an appropriate surgical option for Mrs. Hammons when she saw Dr. Baker in May of 2009, okay?
A. Okay.
Q. Dr. Lowman, have you formed an opinion as to whether Mrs. Hammons was an appropriate candidate for surgery -- surgical repair of her prolapse in 2009?
A. I have.
Q. And what was your opinion?
A. I feel that she was an appropriate candidate for treatment of her prolapse with the PROLIFT®.
Q. Why do you -- why did you arrive at that opinion?
A. Because the PROLIFT® -- the PROLIFT® has been shown to be significantly more successful than traditional repair, in particular in the anterior compartment, which is where her

Page 91

stage IV prolapse was.
Number two, she's at significant risk for recurrence of her prolapse because of her young age, because of her multicompartment prolapse, because of her significant exposures, in terms of the fact that she -- her job required lifting, the fact that she was a two- to three-pack-per-day smoker. She had multiple risk factors for recurrence.
And so she was a high-risk patient and the PROLIFT® is indicated in treating high risk patients.
Q. Prior to May of 2009, did Mrs. Hammons try more conservative treatments of her prolapse?
A. She did.
Q. And what was that more conservative treatment she described?
A. She used a pessary.
Q. And what was Mrs. Hammons' experience with the pessary that she attempted before 2009?
A. It was so uncomfortable for

Page 92

her that she ended up in the emergency room to have it removed.
Q. And you described that one of the reasons why a surgical repair of the prolapse -- the prolapse was appropriate in Mrs. Hammons' case, did that include the severity of the condition that she presented with?
A. Yes.
Q. Dr. Lowman, I'm handing you what has been marked as Defense Exhibit 10003.56.
Are you familiar with this medical record?
A. I am.
Q. Can you tell the jury what this is?
A. This is the operative report from Dr. Baker's procedure.
Q. Let's take a look at what's reflected here.
A. Okay.
Q. First of all, the -- the date is what?

Page 93

A. May 5th, 2009.
Q. And what was Dr. Baker's postoperative diagnosis on this date?
A. Uterine prolapse and cystocele.
Q. When you described earlier that Mrs. Hammons -- one of the reasons why you thought surgery was appropriate was because she had multicompartment failure; is that correct?
A. Yes. Multicompartment prolapse.
Q. Multicompartment prolapse. Is that documented in Dr. Baker's operative note?
A. Yes.
Q. And what were the various compartments that were noted as being in prolapse at this point?
A. Her apical compartment, which is the top of the vagina; and the anterior compartment, which is the front, if that makes sense.
Q. Did Dr. Baker, as part of

Page 94

his operative findings, note any additional evidence of prolapse in Mrs. Hammons' case?
A. He did.
Q. And can you tell, direct me to where that's reflected here?
A. When he dictates his findings, he dictates that the vaginal -- vagina had a grade 4 cystocele and a minimal rectocele.
Q. Would that be yet another prolapse that Mrs. Hammons presented with on this date?
A. Yes.
Q. Now, you told us a moment ago that Mrs. Hammons had a grade 4 cystocele; is that correct?
A. That's correct.
Q. Where does a grade 4 fall on the grading scale of severity of a bladder prolapse like Mrs. Hammons had?
A. It's the most severe.
Q. Are you aware that Dr. Zipper told the jury that Mrs. Hammons,

Page 95

in fact, had a Grade 2 prolapse on this date?
A. I am.
Q. Is Dr. Zipper correct?
A. No.
Q. Why not?
A. Firstly, I think that the most reliable assessment in this case, in considering all of this evidence, is -- are the assessments that are made actually by her treating physicians.
If he determined that she had a grade 4 cystocele, that is most likely to be the most correct assessment.
Secondly, currently, she has been diagnosed with stage III prolapse by both Dr. Zipper and Dr. Jolet. Currently, she is asymptomatic. So if she was symptomatic when she presented to Dr. Baker and she's asymptomatic now, it is most likely that she had worse prolapse when she presented to Dr. Baker.
Q. Did you see Mrs. Hammons' testimony as to whether or not, in May of

Page 96

2009, whether her bladder prolapse was visible to her?
A. Yes, I did.
Q. And what do you recall Mrs. Hammons' testimony being in that regard?
A. She testified that it was visible to her.
Q. Now as is reflected on this operative note, the PROLIFT® was implanted in Mrs. Hammons on May 5, 2009, correct?
A. Correct.
Q. Now, the jury is aware that in December of 2012, Dr. Heit removed portions of Mrs. Hammons' PROLIFT®.
Have you reviewed those records as well?
A. I have.
Q. Have you reviewed Dr. Heit's sworn testimony also?
A. I have.
Q. How did Dr. Heit describe the presentation of -- withdrawn.
Before we get there, between

Page 97

May of 2009 and the summer of 2012, did any of Mrs. Hammons' physicians document any mesh erosion in her case?
A. No.
Q. So now turning to this question of Dr. Heit's care and treatment of Mrs. Hammons.
How did Dr. Heit describe the presentation of Mrs. Hammons' mesh when he saw her in August of 2012?
A. He described that the mesh was rolled and bunched at the bladder neck.
Q. Do you recall whether Dr. Heit gave sworn testimony as to his assessment of how the PROLIFT® mesh became rolled and bunched under Mrs. Hammons' bladder?
A. I do.
Q. Can you tell the jury what your understanding of Dr. Heit's findings, as part of his care and treatment of Mrs. Hammons?
A. Yes. So he -- his

Page 98

conclusion was that the appearance of the mesh was consistent with improper placement.
MR. ISMAIL: Counsel.
BY MR. ISMAIL:
Q. And Dr. Lowman, I'm handing you a copy of Dr. Heit's deposition transcript and his sworn testimony.
Is this information that you reviewed in this case?
A. Yes.
Q. Did you rely upon this information in understanding what symptoms Mrs. Hammons had and when?
A. Yes.
Q. I would ask, Doctor, that you turn to Page 220, and ask whether there's information there that you relied upon to understand how Dr. Heit assessed why the mesh was rolled and bunched underneath Mrs. Hammons' bladder in 2012.
Are you there?
A. I don't think I'm here, but I can follow you on there.

Page 99

Q. If it's easier to follow on the screen.
A. I'll do that.
Q. Is this Page 220 of the transcript?
A. There's different page numbers. You're talking about this one in the corner?
Q. Yes.
A. Let me go to that. Thank you.
Q. Was Dr. Heit, was he asked in his deposition: The bunching, as I think you said earlier, was due to what?
Answer: Well, my hypothesis is related to improper placement.
And then was he asked: And that's to a reasonable degree of medical certainty?
And Dr. Heit answers: Yes.
Is this testimony that you looked to, to understand how Dr. Heit assessed Mrs. Hammons' --
A. Yes.

Page 100

Q. -- condition?
Now, Dr. Lowman, are you aware that Dr. Zipper, on behalf of the plaintiff in this case, has advanced an alternative explanation for how the mesh became rolled and bunched?
A. I am.
Q. What do you understand Dr. Zipper's opinion to be?
A. Dr. Zipper's opinion is that the mesh is rolled -- or was rolled or bunched due to mesh contraction.
Q. So on the one hand, you have Dr. Heit's explanation; and on the other hand, we have Dr. Zipper's explanation?
A. Right.
Q. Did we ask you to analyze those two competing explanations and form an opinion as to which you believe is correct?
A. You did.
MR. SLATER: Objection.
This is beyond the scope of the report of the deposition. We were

Page 101

never given notice of this issue and a comparison of their two opinions. I don't believe it's in the report. I think it's a new opinion.
BY MR. ISMAIL:
Q. Did -- withdrawn.
Did we ask you to consider whether there was any defect in the mesh that led to the condition of the mesh as Dr. Heit found it in 2012?
A. Yes.
MR. SLATER: Objection.
This is beyond the scope of the report as well. This was not analyzed.
BY MR. ISMAIL:
Q. Are you familiar with the opinion advanced by Dr. Zipper in this case?
A. Yes.
Q. And are you familiar with the diagnosis made by Dr. Heit as part of his care and treatment?

Page 102

A. Yes.
Q. And did you consider those two explanations for what happened to Mrs. Hammons with respect to her PROLIFT®?
A. I did.
Q. Did you form an opinion, Doctor, as to what you think happened to Mrs. Hammons' PROLIFT® at the time she presented to Dr. Heit in 2012?
A. I did.
Q. Did you consider Mrs. Hammons' medical records when doing that investigation?
A. I did.
Q. Did you consider the sworn testimony of her doctors?
A. I did.
Q. Did you consider your own clinical experience?
A. Yes.
Q. Did you consider the medical literature on this issue?
A. Yes.

Page 103

Q. All right. Let's discuss the issue of mesh contraction as opined by Dr. Zipper, okay?
A. Okay.
Q. First of all, Dr. Lowman, did you see any indication in the medical records that any of Mrs. Hammons' own doctors diagnosed mesh contraction in this case?
A. No.
Q. Are you familiar with the concept of mesh contraction?
A. I am.
Q. Is that potential complication described in the literature?
A. It is.
Q. Does the description that Dr. Heit gave of how the mesh appeared to him match a description of mesh contraction in a clinical context?
A. No.
Q. And why do you say that?
A. There are -- there is a specific diagnosis of mesh contraction.

Page 104

It's a little bit confusing in the literature because we use that word to mean two different things.
On the one hand, the actual mesh or the mesh vaginal complex can undergo shrinkage. That's called the biomaterial contraction.
On the other hand, there is a clinical syndrome of contraction, as defined by Feiner and Maher in their article on contraction. The clinical syndrome is a patient who presents with severe pelvic pain that's exacerbated by movement, who has reproduction of that pain with palpation of the mesh, and who complains of severe dyspareunia. It's a very specific diagnosis as defined in the literature.
Q. Did Mrs. Hammons present with all three of those criteria?
A. She did not.
Q. Did Mrs. Hammons have any reports of pelvic pain?
A. She did not.

Page 105

MR. SLATER: I just want to state on objection for the record. That opinion and that criteria was not put in the report. This is a new opinion. We object to it and we move to strike it.
BY MR. ISMAIL:
Q. Now, the description that -- withdrawn.
Dr. Zipper told the jury that one of the reasons he thinks the mesh contracted was because the mesh no longer was providing bladder support by August of 2012.
Are you aware of that testimony?
A. I am.
Q. Is Dr. Zipper correct?
A. He's not.
Q. Why do you say that?
MR. SLATER: Objection, again, to this evaluation of Dr. Zipper's opinions. That was not in the report. We weren't given

notice of this.
BY MR. ISMAIL:
Q. Why do you believe -- withdrawn.
Do you believe that in August of 2012 the PROLIFT® was still providing Mrs. Hammons adequate support to her bladder?
A. It was.
Q. And why do you say that?
A. Because Dr. Heit testified that he did not feel that she had a significant cystocele. She had several evaluations by Dr. Lackey and Dr. Heit after the placement of her PROLIFT®, and no one suggested that she had a significant cystocele.
Q. Did you see any indication in Dr. Heit's medical records that he recommended some treatment for a recurrence of bladder prolapse?
A. He did not.
Q. Did you see any indication, from any other physician treating Mrs.

Hammons, following the PROLIFT®, that she needed some treatment for a recurrence?
A. No.
Q. If you have Dr. Heit's deposition testimony still there, on Page 146, you referenced Dr. Heit gave an assessment of Mrs. Hammons' PROLIFT® and whether or not it was providing support in August of 2012.
And do you see, at Page 146, Dr. Heit was asked: During your examination, I take it you did not find that she had a bladder prolapse; is that correct?
And what was his answer?
A. His answer is: Yes, ma'am.
Q. Is that consistent or inconsistent with Dr. Heit's medical records on this question?
A. It's consistent.
Q. Was Dr. Heit further asked: To your knowledge, was the PROLIFT® providing proper anatomical support of Mrs. Hammons' bladder on August 30th,

2012?
A. Yes.
Q. What was his answer?
A. Yes, ma'am.
Q. Do you have an opinion as to whether or not you agree with Dr. Heit's assessment of the effectiveness of the PROLIFT® in Mrs. Hammons' case, in terms of supporting her bladder in this time frame?
A. Yes. It seemed to be working well at supporting her bladder prolapse, as indicated by the fact that none of the treating physicians, after the PROLIFT® was placed, diagnosed her with a significant bladder prolapse, although they did diagnose her with significant prolapse in other compartments.
Q. Now, finally, Dr. Zipper pointed to the pathology report as a basis to conclude that the mesh had contracted.
Did you examine that record

as well?
A. I did.
MR. SLATER: Objection. There's no discussion of this in her -- in Dr. Lowman's report. She's never testified about the pathology report. She's never offered opinions about it. This would be beyond the scope of the report, and we move to preclude this testimony.
BY MR. ISMAIL:
Q. Dr. Lowman, I've not actually done anything yet.
New question.
Dr. Lowman, I'm handing you Defense Exhibit-10020.5.
Are you familiar with this document?
A. I am.
Q. Is this a copy of the pathology report that was prepared based on the mesh that Dr. Heit removed from Mrs. Hammons?

Page 110

A. It is.
Q. Did you review this document?
A. I did.
Q. Are you familiar with it?
A. Yes.
Q. Have you reviewed pathology reports before?
A. I have.
Q. This pathology report, Dr. Lowman, in your opinion, does it provide any indication that Mrs. Hammons' mesh had contracted and that's why it needed to be removed in August -- or in 2012?
A. No.
Q. And why do you say that?
A. This pathology report is a gross description of what was sent to the pathologist for evaluation. Usually, pathologists just describe the fact that they have vaginal mesh there, maybe they have suture there.
They are describing it grossly. They are not looking at --

Page 111

looking at it under a microscope, per se.
Q. So when the pathologist describes a gross description of -- a lot of us use the word "gross" to mean something else in a different contexts.
When you're talking about a pathology review, what is a gross description?
A. That means they're eyeballing it, they're just looking at it, feeling it and then describing it.
Q. Does the pathologist describe contracted mesh in this report? Is that terminology used?
A. She does not, or he.
Q. Based on everything you reviewed, Dr. Lowman, including what you've testified to, was the complication of Mrs. Hammons' PROLIFT® mesh caused by mesh contraction?
A. No.
Q. Did you also consider the explanation offered by Dr. Heit that the reason why the mesh became rolled and

Page 112

bunched was because of surgical technique?
A. Yes.
Q. Did you review Dr. Baker's medical records and his deposition to understand how he implanted the PROLIFT®?
A. I did.
Q. Now, did Dr. Baker describe in his operative note that he implanted the PROLIFT®, quote, per protocol?
A. He did.
Q. Does that answer the question that you were asked to investigate?
A. Not completely, no.
Q. Did you do further analysis to determine what Dr. Baker did or did not do when he implanted the PROLIFT® in Mrs. Hammons?
A. The only thing I have to go on, on what he did was his operative report. He was not specific in his description of his actual implantation of the PROLIFT®, other than the fact that he

Page 113

described that he sutured the PROLIFT® at the apex.
Q. So you indicated that Dr. Baker sutured the PROLIFT® to the apex.
A. Right.
Q. Now, do you have an opinion, Dr. Lowman, as to what caused Mrs. Hammons' mesh to become rolled and bunched to the point that Dr. Heit removed it in 2012?
A. Yes, I do.
Q. Can you tell the members of the jury what your opinion is?
MR. SLATER: Objection. Beyond the scope.
You can answer.
THE WITNESS: I believe that Mrs. Hammons' mesh became rolled or bunched because the mesh was secured to the apex, which is the top of her vagina, and her top -- the top of her vagina was actually prolapsing at the time. And the prolapse of the top of the vagina

Page 114

caused the mesh to sort of fall in this direction and roll or bunch underneath the bladder neck.
BY MR. ISMAIL:
Q. And, Dr. Lowman, have you helped us put together some slides to explain this concept to the members of the jury?
A. I have.
Q. Okay, Doctor, I have up on the screen the first slide.
And you used a lot of terms in your last answer here, and I thought we could use this to orient the members of the jury to your -- the opinion you are giving in this case --
A. Okay.
Q. -- and your basis for it, okay?
A. Okay.
Q. So just real basic.
A. Okay.
Q. We're looking at several of the organs that we've talked a lot about

Page 115

in this trial. And let's orient where we are.
Where is the front of the woman here?
A. The front of the woman is at the -- on the left side.
Q. And if we're going from left to right, first of all, what is this organ here?
A. That's the bladder.
Q. What is this organ here?
A. That's the vagina.
Q. And what is this organ here?
A. That's the rectum.
Q. So as we're going left to right, is all the way to the right the posterior --
A. Simple terms. The back.
Q. The back.
And then the left is the front; is that correct?
A. That's correct.
Q. And is what we depicted here, does this drawing depict a woman

Page 116

with a uterus or no?
A. It does not.
Q. So in terms of Mrs. Hammons, did Dr. Baker do a vaginal hysterectomy before he did the PROLIFT® procedure?
A. He did.
Q. Okay. So now that we're sort of oriented here.
You indicated -- you used the term -- you used a couple of terms in your last answer a moment ago, one of which was vaginal cuff, and one of which was the apex. And I'd like to explain that now if we could.
A. Okay.
Q. Generally speaking, what is the apex, when we're talking about this area of the body?
A. So the apex is the top of the vagina, where those three black lines are located. That whole sort of curvature is considered the apex.
Q. Okay. So let's see if we can do it this way.

Page 117

When you say the "curvature," tell me if I've done it right. Is this, generally speaking, the apex?
A. Right.
Q. You also indicated the term vaginal cuff.
A. Right.
Q. What is the vaginal cuff?
A. The vaginal cuff is the area, the suture line where we have amputated or removed the uterus and cervix. So where those black lines are is where the uterus would normally sit.
In order for us to perform a hysterectomy, we have to cut the uterus out from that area. And those black lines indicate the suture where we've sutured the two ends of the vagina back together.
Q. So in a woman who has had her uterus removed, are the apex and the cuff essentially the same thing?
A. Yes.

Page 118

Q. And you said this was a hole that the -- that Dr. Baker had to make to, basically -- I think the word you used, was amputate the uterus?
A. Right.
Q. And did he have to close that hole back up?
A. Right.
Q. And is that called the cuff?
A. Right.
Q. So what is this blue strip here meant to represent?
A. That's meant to represent the -- where the anterior PROLIFT® would lie.
Q. And is it placed here ordinarily when you're trying to support the bladder?
A. Yes.
Q. Now, you indicated, in one of your last answers, that Dr. Baker sutured the PROLIFT® to the apex.
A. Right.
Q. Can that be done as part of

Page 119

the PROLIFT® procedure?
A. Yes, it's commonly done.
Q. But what did Dr. Baker do in this case that you believe led to the problems later on?
MR. SLATER: Objection.
THE WITNESS: He failed to support --
MR. SLATER: Same objection as before.
BY MR. ISMAIL:
Q. Please begin again.
A. He failed to support the apex at the time of this procedure.
Q. Why do you believe it is significant that Dr. Baker failed to support the apex when he implanted the PROLIFT®?
A. For two reasons. Number one, he attached the mesh to the apex, so failure to support that area is going to put the top of the mesh at risk for falling, if you will.
Secondly, the apex or the

Page 120

top of the vagina, is what we consider the cornerstone of pelvic organ prolapse -- the cornerstone of pelvic organ support. So if the apex is not well supported, it puts the anterior and posterior compartments at risk for failure.
Q. Okay. Can a patient develop an apical prolapse?
A. Yes. She had that.
Q. So when you say "she had that" are you referring to --
A. Mrs. Hammons.
Q. So prior to the time that Dr. Baker implanted the PROLIFT®, had Mrs. Hammons presented with an apical PROLIFT® --
A. She did, yes.
Q. -- prolapse? Sorry.
A. She did.
Q. Did Dr. Baker do any surgical repair that totally fixed the apical prolapse?
A. He did not.

Page 121

Q. Now, is an anterior PROLIFT® designed to support an apical prolapse?
A. It's not.
Q. But I thought you indicated, Doctor, that Dr. Baker sewed the PROLIFT® to the apex or the cuff.
Doesn't that provide support?
A. No, it doesn't.
Q. In addition to the PROLIFT®, did Dr. Baker, I think you indicated did a vaginal hysterectomy on this day; is that right?
A. He did.
Q. Does a vaginal hysterectomy totally fix an apical prolapse?
A. No, it doesn't. The uterus is an innocent bystander, if you will.
The primary problem with pelvic organ prolapse is the vagina itself. The organs that are involved are innocent bystanders. The bladder is resting, as you can see in this picture, on the front wall of the vagina. The

Page 122

rectum rests behind the back wall. The uterus and cervix, if it was in the picture, would be resting at the top.
It's the vaginal walls that are dropping and falling in the pelvic organ prolapse. It's not a problem with the bladder or the rectum or the uterus.
Q. Did Mrs. Hammons, after the implantation of the PROLIFT®, develop a worsening apical prolapse?
A. She did.
Q. What effect did that have on the PROLIFT®, which Dr. Baker sewed to it?
A. It didn't allow it to lie flat in that compartment.
Q. And have you helped us prepare some slides to represent that phenomenon?
A. I have.
Q. This first slide here, orient the jury, if you could, to what's happening in comparison to the slide we just looked at?

Page 123

MR. SLATER: I just want to state again, I object to this testimony. I don't believe this was spelled out in the report.
BY MR. ISMAIL:
Q. Go ahead, ma'am.
A. So this picture is representing apical prolapse or the descent of the top of her vagina after the mesh has been inserted.
As the vagina is dropping -- so if this is the mesh and it's been placed in the vagina here and they're secured to one another, as the anterior vagina and the apex of the vagina falls, it's going to pull that mesh forward. That's what that picture is representing.
Q. So in this diagram here, do we have an example of an advancing apical prolapse?
A. Yes.
Q. And is that what was happening in Mrs. Hammons' case after May of 2009?

Page 124

A. Yes.
Q. What effect did that have on the mesh that was sewn to it?
A. It caused it to pull forward or to roll or bunch.
Q. Did that process continue to the time that Mrs. Hammons found her way to Dr. Heit in 2012?
A. Most likely.
MR. SLATER: Counsel, just one other thing. We've never seen these diagrams. They were never suggested by the report, they were never provided. We never had any ability to meet this in our case. I'm putting that on the record as well. Along with our objection that these opinions are new opinions.
MR. ISMAIL: I'm not sure if you got spoken over, Doctor, so let me re-ask the question.
BY MR. ISMAIL:
Q. Did the process of Mrs.

Page 125

Hammons' apical prolapse continue to the time that she was ultimately referred to Dr. Heit in 2012?
A. It did.
Q. So if we continue the process forward, in this next slide, do you further depict an apical prolapse to the degree that Mrs. Hammons had when she saw Dr. Heit?
MR. SLATER: Same objection.
THE WITNESS: Right. Yes. This shows that that prolapse has progressed.
I believe that her prolapse was even more severe than this picture predicts. But, yes. Or depicts is what I meant to say.
BY MR. ISMAIL:
Q. So between Dr. Baker in may of 2009 and Dr. Heit in August of 2012, at any time did any physician provide support for Mrs. Hammons' apex?
A. No.
Q. Did her apical prolapse

Page 126

continue to develop over time during that entire time period?
A. Yes.
Q. And is what you're showing here, that blue line that's sort of rolled and bunched, is that how you understand Mrs. Hammons' mesh was presenting to Dr. Heit in 2012?
A. Yes.
Q. When was the first time that a doctor provided any surgical repair of Mrs. Hammons' apical prolapse?
A. When Dr. Heit operated on her.
Q. Now, do you believe the failure to support the apex, of Dr. Baker in May of 2009, was that a mistake?
A. Yes.
Q. Do you believe that the failure to support the apex in the subsequent apical prolapse, did that have any contribution to how the mesh became rolled and bunched in 2012?
MR. SLATER: Objection to

Page 127

this. Again, there's no opinion that it was a mistake. It was not phrased this way. We object to this line.
MR. ISMAIL: I'll rephrase.
MR. SLATER: And, again, object to this question again, because I just went through the report, these opinions are not there.
MR. ISMAIL: Let me rephrase.
BY MR. ISMAIL:
Q. Do you believe that the presentation of rolled and bunched mesh, do you believe that is a function of surgical implant technique?
A. Yes.
Q. The surgical -- and whose surgical implant technique are you referring to?
A. Dr. Baker's.
Q. What was the surgical implant technique issue that you believe

Page 128

led to the rolled and bunched mesh?
A. The lack of supporting the apex that he sutured the mesh to.
Q. And have you described for the jury why you believe that that surgical technique decision of Dr. Baker's led to the mesh being in the condition it was in 2012?
A. Yes.
Q. Now, let's talk about the turn about of the consequences of that rolled and bunched mesh in 2012, okay?
A. Okay.
Q. In the summer of 2012, did Mrs. Hammons develop urinary incontinence symptoms?
A. She did.
Q. Doctor, in your clinical experience, do you treat patients with urinary incontinence?
A. I do.
Q. Just briefly, are there different types of incontinence conditions that a patient can develop?

Page 129

A. There are.
Q. Can you describe some of those, briefly, for the jury?
A. Sure. The most common reasons to have urinary incontinence in the female pelvic -- female patient population is overactive bladder, where the patient experiences incontinence because of not being able to make it to the bathroom in time; stress incontinence, where the patient experiences urinary incontinence with coughing, sneezing and laughing; overflow incontinence, where the patient experiences incontinence with difficulty voiding.
Q. Prior to receiving the PROLIFT®, did Mrs. Hammons have indications in her medical record of having incontinence symptoms?
A. I don't believe so. She may have had mild stress incontinence.
Q. Did -- was that documented in the records of her primary care

Page 130

physician, Dr. Royer?
A. I believe so.
Q. What type of incontinence did Dr. Heit diagnose Mrs. Hammons as having in 2012?
A. Insensible urine loss.
Q. Is that a condition you're familiar with?
A. It is.
Q. What is insensible urine loss?
A. That means that the patient is experiencing incontinence without sensation.
Q. Now, Doctor, do you agree with Dr. Heit that the rolled and bunched mesh may have been contributing to Mrs. Hammons insensible urine loss?
A. Yes, it may have.
Q. Have you described for the jury what you believe happened as to how the rolled -- the mesh became rolled and bunched in 2012?
A. I have.

Page 131

Q. Is that in reference to the apical prolapse you've described already?
A. Yes.
Q. Now, Dr. Heit, did he do a procedure to remove the mesh from the bladder neck?
A. Yes, he did.
Q. Do you agree with Dr. Heit's decision to do that?
A. Yes, I do.
Q. What happened in particular to Mrs. Hammons' complaints of incontinence after Dr. Heit did his procedures in the end of 2012 and early 2013?
A. They resolved.
Q. Have you seen any indication in the medical records, since early 2013, that Mrs. Hammons has had any complaints of incontinence the likes of which she had before she saw Dr. Heit?
A. No.
Q. Have you reviewed Mrs. Hammons' sworn testimony on the issue of

Page 132

whether she has any complaints of incontinence since Dr. Heit's care and treatment of her?
A. I have.
Q. And does she have any complaints that she's testified to on the issue of incontinence?
A. No.
Q. Did Dr. Heit, as part of his assessment of Mrs. Hammons, assess her bladder capacity?
A. He did.
Q. Did he do so both before and after the procedures he did -- offered her to treat her incontinence symptoms?
A. He did.
Q. Dr. Lowman, I'm going to provide you a copy of Defense Exhibit-10043.22 and ask that you confirm that this is a medical record that you reviewed in this case?
A. Yes, it is.
Q. Can you tell the members of the jury what this is?

Page 133

A. This is a consultation note from Dr. Heit.
Q. And to whom is it sent?
A. It was sent to Dr. Lackey.
Q. And does -- what's the date of it?
A. January of 2013.
Q. Does Dr. Heit inform Dr. Lackey here of some of the testing that he's done on his patient, Patricia Hammons?
A. He does.
Q. Does that include an assessment of bladder capacity?
A. It does.
Q. And is that under the first paragraph?
A. Yes.
Q. And towards the end of that paragraph, what does Dr. Heit say is Mrs. Hammons bladder capacity?
A. He says that her capacity is normal.
Q. Have you seen any indication

Page 134

from any of her treating physicians, after January of 2013, to suggest any change in Mrs. Hammons' bladder capacity?
A. No.
Q. What does this tell you, as a specialist in this field, as to whether or not Mrs. Hammons has low bladder compliance?
A. That she didn't have it.
Q. Have you seen any indication in the medical records that any of Mrs. Hammons' treating physicians have diagnosed her with low bladder compliance?
A. No.
Q. Now, to the extent Mrs. Hammons has reports today of feelings of urgency, that she has to use the restroom more frequently, what's that called in urogynecology?
A. Overactive bladder.
Q. Are there various factors that can lead a patient to develop overactive bladder?

Page 135

A. There are.
Q. What are some of those?
A. The most common is irritant exposure; so exposure to things that irritate the bladder and cause it to be overly contractive. That would include coffee, tea, sodas, alcohol, carbonated beverages, tobacco.
Having pelvic organ prolapse in particular, a cystocele, is associated with irrelevant -- we call it irritated voiding symptoms or overactive bladder as well.
Q. Are there medications that can be offered to a patient to help treat these symptoms of having to go more frequently?
A. Yes, there are.
Q. Have you seen any indication in the medical records, following Dr. Heit's treatment of Mrs. Hammons, that she's been offered or has taken any of these medications to treat this overactive bladder symptom you've

Page 136

described?
A. I haven't.
Q. Dr. Zipper opined that Mrs. Hammons is at risk for future kidney injury.
Are you familiar with that testimony?
A. I am.
Q. And have you formed a view as to whether Dr. Zipper is correct or not?
A. Yes.
MR. SLATER: One second, objection. Not expressed in the report.
BY MR. ISMAIL:
Q. Dr. Lowman, can you please tell us what your opinion is as to Dr. Zipper's suggestion that Mrs. Hammons is at risk for future kidney problems?
A. I think that's ridiculous.
Q. Why do you say that?
A. Because impaired compliance of the bladder has got to be very severe

Page 137

in order for it to lead to kidney failure, so severe that the treating physicians often consider diversion, is what we call it, but, basically, moving urine that goes to the bladder to urine that goes to the bowel.
Q. Have you seen any indication, Dr. Lowman, that any physician has diagnosed Patricia Hammons with the severe bladder compliance condition that you've just described?
A. No.
Q. Does Mrs. Hammons, today, have any compromised renal function?
A. No.
Q. In terms of the most recent testing done, how is her kidney function?
A. It's normal.
Q. Doctor, we talked before about that a patient can present with multiple organ prolapse.
Do you recall that discussion?
A. Uh-huh.

Page 138

Q. Yes?
A. Yes.
Q. Are patients who developed prolapse in one -- with one organ at an increased risk for developing it in other organs?
A. Yes.
Q. If a patient has prolapse in -- with multiple organs, do you try to treat all those prolapses when you're a treating physician?
A. Yes.
Q. Why?
A. Because it makes sense to treat everything that's broken at the time that you're treating pelvic organ prolapse.
But, furthermore, it -- if you don't treat it, it's likely to progress.
Q. So what are the consequences of leaving a particular prolapse untreated in a patient?
A. It kind of -- you know, it

Page 139

depends on the compartment that you're talking about.
If you're talking about the apex, you put that patient at risk for developing prolapse in alternative compartments, because apical prolapse, or not supporting the apex, makes it very difficult to support whatever compartment you're trying to support, either the anterior compartment or the posterior compartment.
If it's, say, just the posterior compartment, the major risk is that that compartment might progress; if there's a mild prolapse there, it might get worse.
If you don't treat the apical part, and you're -- say you're -- let me start over.
Q. Let me start with a new question. I'll withdraw the prior question and start with a new question.
A. Okay.
Q. What are the consequences of

Page 140

failing to treat a prolapse that is presenting to a physician?
A. It may progress.
Q. Now, we already looked at a record, and I'll put it back up on the screen, that Dr. Baker, before the PROLIFT®, assessed that Mrs. Hammons had multiorgan prolapse; is that correct?
A. That's correct.
Q. One of which was the bladder prolapse; is that right?
A. Yes, that's right.
Q. And was the PROLIFT® the procedure he did to support that?
A. Yes.
Q. And you already indicated that she had a uterine prolapse or an apical prolapse?
A. Yes.
Q. Was there any treatment offered to Mrs. Hammons at this point to treat that prolapse?
A. There was not.
Q. You also indicated that she

Page 141

had a rectocele in May of 2009.
Was there any surgical repair offered of that prolapse?
A. No.
Q. Now, subsequent to Dr. Baker's procedure, did Mrs. Hammons present to another physician with a prolapse of a different organ?
A. Could you repeat the question for me?
Q. Sure.
Subsequent to Dr. Baker's procedure, did Mrs. Hammons see a different physician because she developed prolapse in a different organ?
A. She did.
Q. And who was that physician?
A. Dr. Lackey.
Q. What type of prolapse did Dr. Lackey diagnose?
A. A rectocele.
Q. Did Dr. Lackey do a surgical procedure to repair the rectocele?
A. He did.

Page 142

Q. What type of procedure did he do?
A. He did a traditional repair called a posterior colporrhaphy.
Q. Is that the native tissue surgery that the jury's heard about?
A. Yes, it is.
Q. At that same time, did Dr. Lackey find yet another prolapse in connection with the surgery he did on Mrs. Hammons?
A. He did.
Q. What is that?
A. An enterocele.
Q. What kind of organ prolapse is that?
A. It's bowel prolapse.
Q. Did Dr. Lackey repair that prolapse in the same procedure?
A. He did.
Q. Now, Dr. Lowman, did Mrs. Hammons' use or implantation of a PROLIFT® cause her to develop a rectocele?

Page 143

A. No, it did not.
Q. Why do you say that?
A. She had a rectocele at the time of the PROLIFT® procedure.
Q. Did the PROLIFT® cause the rectocele to get worse?
A. No, it didn't.
Q. Why do you say that?
A. Because fixing one compartment doesn't cause or worsen prolapse in other compartments.
Q. Did the PROLIFT® cause Mrs. Hammons to develop the bowel prolapse?
A. No, it didn't.
Q. Is that for the same reasons you've just described?
A. Right.
Q. Did you see any indication in the medical records that any of Mrs. Hammons' treating physicians assessed that the PROLIFT® was the cause of either the bowel prolapse or the rectocele?
A. No.
Q. What does it tell you

Page 144

instead -- withdrawn.
What does it tell you, that Mrs. Hammons has developed prolapse in multiple organs, the bladder, the rectum, the bowel and the apex?
A. It's just an indication of the severity of her pelvic floor dysfunction.
Q. And when you say it's "an indication of the severity of her pelvic floor dysfunction," what do you mean by that?
A. I mean that she has so many risk factors for developing pelvic organ prolapse. Part of that is pelvic floor dysfunction, sort of the fact that her connective tissues aren't working appropriately to hold her organs up. That affects the pelvis globally. Even though it's just manifesting in the anterior compartment initially, the other compartments are also at risk.
Q. Now, did Dr. Heit, I think you indicated he did a procedure, as

Page 145

well, to provide surgical repair of one of the prolapses Mrs. Hammons had?
A. Yes.
Q. So I think we started this discussion a while ago mentioning the fact that Mrs. Hammons has had three different types of prolapse procedures; is that correct?
A. That's correct.
Q. One of which was the PROLIFT®?
A. Right.
Q. One of which was the native tissue surgery?
A. Right.
Q. And another of which was using a graft from a pig to support her organs; is that correct?
A. That's correct.
Q. Of the three surgeries that Mrs. Hammons had, did any of them fail?
A. Yes.
Q. Which ones?
A. All except the PROLIFT®.

Page 146

Q. The native tissue surgery that Dr. Lackey did, did that result in a recurrence?
A. It did.
Q. The pig graft procedure that Dr. Heit did, did that ultimately fail, too?
A. It did.
Q. Up until the time that Dr. Heit removed the PROLIFT®, had the PROLIFT® failed?
A. No.
Q. Is it surprising to you that Dr. Lackey's native tissue surgery failed?
A. It's not, no.
Q. Why?
A. For the reasons that I just discussed. The fact that she has so many risk factors for recurrence.
Q. Is it surprising to you that even the biologic graft that Dr. Heit did failed?
A. It's not.

Page 147

Q. Dr. Lowman, I want to now turn to the question of dyspareunia.
A. Okay.
Q. In your patients, do you see complaints related to pain with intercourse?
A. I do.
Q. What are some of the factors that can lead a woman to develop pain with intercourse?
A. Vaginal atrophy, levator myalgia, interstitial cystitis, prior surgeries.
Q. Can a prolapse itself lead to painful sexual intercourse?
A. It can.
Q. Did Mrs. Hammons have some of those very risk factors that you just described?
A. She did.
Q. Did you see any indication in the medical records that Mrs. Hammons had vaginal atrophy?
A. Yes.

Page 148

Q. Is vaginal atrophy associated with menopause and the loss of estrogen?
A. It is.
Q. Did Mrs. Hammons, over time, have multiple vaginal surgeries?
A. She did.
Q. The vaginal hysterectomy that Mrs. Hammons had, is that associated with dyspareunia?
A. It can be.
Q. The native tissue surgery that Dr. Lackey did, is that associated with dyspareunia?
A. It is.
Q. The surgery that Dr. Heit did, is that associated with dyspareunia?
A. It is.
Q. And you've already described for us that you have looked at this question yourself as to whether dyspareunia is associated with the PROLIFT®, correct?
A. Right.

Page 149

Q. Now, when did Mrs. Hammons first report dyspareunia to one of her physicians?
A. She first reported dyspareunia to Dr. Baker at her postop follow-up 11 weeks after her PROLIFT® surgery.
Q. Okay. So I'm now providing you Defense Exhibit-10016.10, and ask if you can confirm this is a medical record you reviewed.
And tell the members of the jury what it is.
A. This is a medical record that I reviewed. This is a physical examination note, or a progress note, by Dr. Baker.
Q. Does this relate at all to this question of when Mrs. Hammons first reported dyspareunia?
A. It does. This is the first instance of they are -- or at least it being documented that she was reporting dyspareunia.

Page 150

Q. Okay. So the date is July 20th, 2009; is that correct?
A. That's correct.
Q. And does Dr. Baker document Mrs. Hammons' complaints and his findings on that date?
A. He does.
Q. Did Dr. Baker do a vaginal exam on this day?
A. He did.
Q. Dr. Lowman, when you're examining a patient who has reported pain, do you sometimes attempt to reproduce the pain?
A. Yes, we do.
Q. Why do you do that?
A. It gives us an indication of the cause of the pain.
Q. Did Dr. Baker do that in this case?
A. He did.
Q. Does the particular spot or location that leads to pain, does it help tell you, as a doctor, what's going on

Page 151

with that patient?
A. It does.
Q. Did Dr. Baker document in this record where he was able to reproduce Mrs. Hammons' pain?
A. He did.
Q. And can you tell the jury where that was?
A. He said that the pain is on the back cuff.
Q. Is that what I've highlighted here in this record?
A. It is.
Q. When we've talked about the back cuff, is that -- is that the vaginal cuff you told the jury about?
A. Right.
Q. Okay. Is this finding of Dr. Baker significant to you in understanding what was causing Mrs. Hammons' pain on that day?
A. It is.
Q. What do you believe, Doctor, was the most likely explanation for why

Page 152

Mrs. Hammons was experiencing painful sexual intercourse in July of 2009?
A. I think the most likely -- the most likely reason that she was experiencing pain at that time was from her vaginal cuff incision --
Q. And --
A. -- from the hysterectomy.
Q. So the vaginal cuff incision.
Which of the surgical procedures that Dr. Baker did required the vaginal cuff incision?
A. The vaginal hysterectomy.
Q. And why do you say it most likely is related to that procedure rather than the PROLIFT®?
A. Because he reports that the pain is on the back, which is in the opposite compartment where the PROLIFT® was placed. And he reports that it's at the cuff.
Q. So is the -- I think we looked earlier at that anatomical

Page 153

drawing.
A. Uh-huh.
Q. If we look back at this drawing here, the PROLIFT® is placed at the front?
A. That's right.
Q. And where is the back cuff in this drawing?
A. Right there. Right where you're indicating it.
Q. So to the right of where the stitches are located?
A. Right. Or it can even be a little further, that whole curve is considered the back cuff.
Q. Okay. And is that location of pain consistent with the incision done for the hysterectomy?
A. It is.
Q. Is it at all surprising to you to have a patient who attempted intercourse six weeks after a vaginal hysterectomy reporting pain?
A. That's not surprising.

Page 154

Q. When did Mrs. Hammons next report pain with sexual activity?
A. She next reported pain when she presented to Dr. Lackey.
Q. Was that at the end of 2009?
A. Yes.
Q. I'm now handing you what we've marked as Defense Exhibit-10043.4. Dr. Lowman, is this a record you reviewed and considered in this case?
A. It is.
Q. Can you tell the jury what it is?
A. This is a progress note by Dr. Lackey.
Q. And the date of it?
A. November 30th, 2009.
Q. Did Mrs. Hammons report to Dr. Lackey pain with sexual activity on this -- at this visit?
A. She did.
Q. Now, did Mrs. Hammons tell Dr. Lackey about her prior surgery with Dr. Baker?

Page 155

A. She did.
Q. And is that documented here?
A. It is.
Q. Can you direct us to where that is?
A. In the beginning of his assessment, he says that she had a hysterectomy and bladder repair in May of this year. The uterus was coming out and the bladder was dropped. She thinks they used mesh and those symptoms are better.
Q. Did Dr. Lackey do an examination on that date as to this question of whether the mesh was adequately supporting Mrs. Hammons' bladder?
A. He did.
Q. And what did he assess on that date?
A. He said that her bladder is well supported.
Q. Did Dr. Lackey also assess what he believed was causing Mrs. Hammons' pain with sexual activity?

Page 156

A. He did.
Q. Now, did you review Dr. Lackey's deposition?
A. I did.
Q. Was Dr. Lackey asked, and provided sworn testimony on this issue?
A. He did.
Q. Do you recall what Dr. Lackey testified to was -- what was his belief as to what was causing Mrs. Hammons' pain, towards the ends of 2009, with sexual activity?
A. It was his opinion that her pain was being caused by the prolapse.
Q. Did Dr. Lackey also mention that atrophy may be -- vaginal atrophy may be contributing to her pain?
A. Yes, he did.
Q. Dr. Lowman, do you see any reason to disagree with Dr. Lackey's conclusion about his own patient and what was causing her pain with sexual activity?
A. No.

Page 157

Q. Can vaginal atrophy lead to pain?
A. Yes.
Q. Can a severe rectocele, the likes of which Mrs. Hammons had, lead to pain with sexual activity?
A. Yes.
Q. And you've already described for the jury that Dr. Lackey did a surgery to help correct the prolapse that Mrs. Hammons had developed in other organs outside of the bladder, correct?
A. Yes.
Q. In 2010, did Mrs. Hammons report to any of her healthcare providers any complaints of dyspareunia?
A. Not that I'm aware of.
Q. In 2011, did Mrs. Hammons report to any of her healthcare providers any complaints of dyspareunia?
A. No.
Q. Now, we already discussed with the jury Dr. Heit's treatment of Mrs. Hammons, beginning in the summer of

2012.
Do you recall that?
A. Yes.
Q. To the extent that Mrs. Hammons was sexually active in that period of time, what do you believe would be the factors that would cause her to have pain with sexual activity?
And, again, we're talking about the period of time around Dr. Heit's treatment, when he found the mesh rolled and bunched.
A. I think her painful intercourse was most likely, at that time, multifactorial, for all of the reasons that we just talked about. So she demonstrated vaginal atrophy at the time that she presented to Dr. Heit.
She demonstrated stage III prolapse at the time that she presented to Dr. Heit. He also described her having a foreshortened vagina. All of those things can contribute to dyspareunia.

And he did palpate her mesh and reproduce pain there, so I do think that was likely contributing to her dyspareunia as well.
MR. ISMAIL: We need to change the tape.
VIDEO TECHNICIAN: Going off the record at 4:20 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 4:28 p.m.
BY MR. ISMAIL:
Q. Dr. Lowman, did -- I want to turn now to the period of time after Dr. Heit did his procedures, the end of 2012, early 2013, okay?
A. Okay.
Q. I'm going to hand you what we marked as Defense Exhibit 10039.3.
Is this a medical record you reviewed in this case?

A. It is.
Q. Can you tell the jury what this is?
A. This is Dr. Heit's postop assessment in April of 2013.
Q. When you say postop, that's after the operations he performed?
A. After the operations he performed, yes.
Q. Was this Dr. Heit's last visit with Mrs. Hammons?
A. It is.
Q. Now, so we have at the top April 22nd, 2013; is that correct?
A. That's correct.
Q. Did Dr. Heit do a physical examination on this date?
A. He did.
Q. And what did he note?
A. He noted a normal vagina, other than atrophy. No tenderness on examination.
Q. And is that significant to you?

A. It is.
Q. Tell us why.
A. Because she initially presented with tenderness on examination and now is not, after having excised the mesh.
She also has vaginal atrophy.
Q. Is vaginal atrophy that condition that you've described as being associated with painful sex?
A. It is.
Q. Did Dr. Heit, in this visit, give any advice to Mrs. Hammons as to whether or not he believed she could resume sexual activity?
A. Yes, he did.
Q. And what did he document here?
A. Okay to proceed with coitus.
Q. Is that -- what does that mean in non --
A. Coitus is sexual activity.
Q. And is that finding or is

Page 162

that recommendation significant to you in any way?
A. It is.
Q. Tell us why.
A. I think that Dr. Heit is basically saying, you know, the problems that you presented to me with are now resolved, it's fine for you to continue -- or to resume your usual activities.
Q. Since early 2013, Dr. Lowman, have you seen any indication that -- withdrawn.
In this record that we're looking at here, did Dr. Heit document any concern that Mrs. Hammons -- withdrawn.
Do you have an opinion, Dr. Lowman, as to whether or not mesh was causing Mrs. Hammons any pain with intercourse after her care and treatment by Dr. Heit?
A. That would be unlikely, no.
Q. And what do you base that

Page 163

on?
A. My clinical experience, the evaluation of mesh complications in the literature, and Dr. Heit's assessment.
Q. Now, as of April of 2013, had Dr. Heit done procedures to remove the mesh from the vagina?
A. He did.
Q. And is that significant to you in considering whether or not, after his care and treatment, Mrs. Hammons' prior use of a PROLIFT® had any relation to complaints of painful sexual activity?
A. Current complaints?
Q. Correct.
A. You're asking -- no.
Q. Tell us -- tell us why that is significant.
A. It's significant because Dr. Heit's assessment was that he felt that the rolled and bunched mesh was contributing to her pain. After he excised the mesh, he's communicating in this note, in my opinion, that he does

Page 164

not feel like that condition currently exists.
So if she does have pain with intercourse at this time, it is most likely not related to the mesh.
Q. If Mrs. Hammons is sexually active since her treatment with Dr. Heit and is reporting pain, what do you believe to be the most likely explanation for that pain?
A. All of the other potential things that we talked about, which would include vaginal atrophy, the fact that she may or may not have a shortened vaginal length, and the multiple surgeries that she has been exposed to.
Dr. Jolet, in her evaluation, also documented the condition of levator myalgia, which is where the muscles around the vagina spasm, and that can cause pain with intercourse as well.
Q. How about going forward, Dr. Lowman, is there any reason to believe that Mrs. Hammons' implantation with a

Page 165

PROLIFT® in 2009 would cause her painful intercourse in the future?
MR. SLATER: One second, counsel. I just want to move and -- object and move to strike the last answer. Reference to Dr. Jolet's exam by this witness is inappropriate, since that is a defense expert who is not testifying in trial.
MR. ISMAIL: Let me re-ask a prior question.
BY MR. ISMAIL:
Q. Dr. Lowman, I guess the judge will decide whether the first answer is acceptable or not. But let me re-ask it and ask that you not make reference to Dr. Jolet, okay?
A. Okay.
Q. If Mrs. Hammons is sexually active since her treatment with Dr. Heit and is reporting pain, what do you believe the most likely explanation for that pain to be?

Page 166

A. The potential conditions that she currently has, or at least did have at that time, that may lead to her having dyspareunia are vaginal atrophy, a foreshortened vagina, and Dr. Zipper testified that she had pain with palpation of the anterior vaginal wall on his exam.

That, coupled with urgency and frequency, is also consistent with interstitial cystitis, which is a condition that can cause painful intercourse.

Q. Now, does --

MR. SLATER: Move to strike that answer also. The interstitial cystitis opinion, which has absolutely no basis whatsoever. That's never been found by any doctor.

BY MR. ISMAIL:

Q. Doctor, do you believe that since Mrs. Hammons' treatment with Dr. Heit, has there been documentation of her

Page 167

having vaginal atrophy?

A. Since the treatment of Dr. Heit? Yes.

Q. Does -- do you believe that Mrs. Hammons' vaginal atrophy to be contributing to her reports of pain with any sexual activity that she's engaged in since Dr. Heit's treatment?

A. Yes.

Q. Do you believe that the procedures, the surgical procedures he's undertaken, specifically the vaginal hysterectomy and the native tissue surgery of Dr. Lackey, to be contributing to any pain that Mrs. Hammons may be experiencing since her treatment with Dr. Heit?

A. Could you ask that question again?

Q. Yes.

Let me ask it this way:

Since January of 2013, has any doctor ever found, on examination, that he or she could feel mesh in Mrs. Hammons?

Page 168

A. No.

Q. Does that include Dr. Zipper?

A. Yes.

Q. Since January of 2013, has any doctor ever noted that mesh was visible in Mrs. Hammons' case?

A. No.

Q. Does that include Dr. Zipper?

A. Yes.

Q. Are those findings significant to you in answering the question of whether mesh is playing any role in any symptoms that Mrs. Hammons is reporting currently?

A. Yes.

Q. Tell us why.

A. Because if the presence of mesh is causing dyspareunia, removing the mesh usually resolves the dyspareunia.

Q. And the fact that there's no mesh palpable or visible in Mrs. Hammons since 2013, is that a significant

Page 169

finding?

A. It is.

Q. Does that help answer this question of whether or not the mesh is causing Mrs. Hammons any symptoms since early 2013?

A. It does.

Q. Now, the jury has seen reference to these straps or arms of an anterior PROLIFT®.

You're obviously familiar with what the PROLIFT® looks like, correct?

A. Yes.

MR. SLATER: Objection. There's no discussion of any issues with the arms in the report.

BY MR. ISMAIL:

Q. The jury has seen a surgical video, at least a portion of it, of implantation of a PROLIFT®.

You're obviously familiar with the PROLIFT® procedure?

Page 170

A. I am.
Q. Now, the straps that are part of the PROLIFT® as it comes out of the box, is that entire strap still in Mrs. Hammons?
A. No.
Q. Why is do you say that?
A. Because a significant portion of the strap is cut at the time of surgery.
Q. So if the jury saw a video in which the arms are pulled through these plastic tubes called a cannula --
A. Right.
Q. -- what happens next in the surgery?
A. Once the mesh is appropriately positioned, the cannulas are removed and the mesh is cut at the level of the patient's skin.
Q. So if, during Dr. Zipper's examination, the PROLIFT® out of the box was held up to the jury and it was suggested that the strap, or the entire

Page 171

arm of the mesh is still in Mrs. Hammons, is that accurate?
A. That's misleading --
MR. SLATER: Objection. Mischaracterizes and foundation.
THE WITNESS: That would be inaccurate.
BY MR. ISMAIL:
Q. Now, is the strap that -- is there a portion of that arm or strap that's still in Mrs. Hammons, potentially?
A. Yes.
Q. Is that in contact with the vagina?
A. Not according to Dr. Heit's testimony or his operative report.
Q. Is there any reason to expect that that small portion of the strap would cause Mrs. Hammons any problems going forward?
A. No.
Q. Why do you say that?
A. In the studies that evaluate

Page 172

mesh contraction and mesh complications, it is documented that the majority of the pain that is caused in that situation is from tension across the mesh body from the mesh arms.
So if you relieve the connection or relieve that tension across the mesh, then you are likely to relieve the patient's symptoms.
MR. SLATER: Objection. Move to strike. Improper use of medical literature.
THE WITNESS: That's been my clinical experience as well.
BY MR. ISMAIL:
Q. Dr. Lowman, in your clinical practice, have you had experience treating women and providing relief for pain of dyspareunia?
A. I have.
Q. Do you see any indication, since Dr. Heit's treatment with Mrs. Hammons, that she's ever been offered treatment for dyspareunia?

Page 173

A. No.
Q. What types of treatments are you familiar with in women who have reported pain with sexual activity?
A. Oh, there are several. It depends on the diagnosis. If a patient presents with interstitial cystitis, which is definitely a real condition, the jury can Google it, but it's there --
Q. Let's start over. That's going to cause the judge to be upset. So let's start over.
A. It's real.
Q. I know.
A. He said I'm making it up.
Q. We're not inviting the jury to Google anything. So we'll start over with a new question, okay?
A. Fine.
Q. What types of treatments are available for women who have reports of dyspareunia?
A. There are several treatments. It depends on the diagnosis

Page 174

causing the dyspareunia. In the case of interstitial cystitis, we use several different medications.

You can perform cystoscopy with hydrodistention. I mean, there are a number of different treatment options.

In the case of levator myalgia, the usual therapies include physical therapy. We can inject sort of numbing medication, what we call trigger point injections, to help relieve pain in that situation. We can actually inject Botox into the muscles themselves to relieve the spasm that's causing the pain.

So it just depends on what the cause is.

Q. Have you had success in treating women who have reports of dyspareunia?

A. Yes.

Q. I want to turn now to this discussion of vaginal length. You mentioned that in one of your answers a

Page 175

moment ago, okay?

A. Okay.

Q. Was there a measure of total vaginal length in Mrs. Hammons before Dr. Baker's surgery in May of 2009?

A. Not that I'm aware of, no.

Q. When was the first time any physician recorded a measure of total vaginal length for Mrs. Hammons?

A. Dr. Heit's evaluation.

Q. And do you recall what Dr. Heit measured?

A. He said it was 7 centimeters.

Q. Now, did Mrs. Hammons, prior to seeing Dr. Heit, undergo certain surgeries that would be expected to reduce her total vaginal length?

A. She did.

Q. What were those surgeries?

A. Namely, the vaginal hysterectomy that she had, as well as the enterocele repair without supporting the apex.

Page 176

Q. The -- you mentioned that there was no measure of total vaginal length before Dr. Baker's surgeries, correct?

A. That's correct.

Q. If we were to assume that Mrs. Hammons had a 10 centimeter vaginal length, would the vaginal hysterectomy and the native tissue surgery alone be sufficient to explain her current vaginal length?

MR. SLATER: Objection.

THE WITNESS: They would.

BY MR. ISMAIL:

Q. And what do you base that upon?

A. Upon the literature and my clinical experience.

Q. Now, just a few more questions, Dr. Lowman.

You've discussed with the jury several opinions that you've offered today, both about the PROLIFT® device and procedure and Mrs. Hammons in particular.

Page 177

And I'd like to review those now, if we could.

A. Okay.

Q. Dr. Lowman, based on all the work that you have done, your clinical experience, the literature, your work as a researcher, was the PROLIFT® a safe and effective option to treat Mrs. Hammons' pelvic organ prolapse in May of 2009?

A. Yes.

Q. Based on all the work you've done, your clinical experience and the medical literature, did the PROLIFT® cause Mrs. Hammons to develop a prolapse in other organs?

A. No.

Q. Did Mrs. Hammons' initial reports of painful sexual intercourse in 2009 have anything to do with the PROLIFT®?

A. No.

Q. Is that for the reasons you've described for the jury so far today?

Page 178

A. Yes.
Q. Did mesh contraction cause Mrs. Hammons' mesh to roll and bunch under the bladder neck, as found by Dr. Heit?
A. No.
Q. What did?
A. Not supporting the vaginal apex at the time that the mesh was secured to the vaginal apex.
Q. Since the removal of mesh has, the PROLIFT® caused Mrs. Hammons any complications, in your view?
A. Not that the medical records demonstrate, no.
Q. Does Mrs. Hammons have any ongoing complications that you believe is due to her PROLIFT®?
A. No.
Q. Have any of Mrs. Hammons' doctors diagnosed any complications from Mrs. Hammons' PROLIFT® since January of 2013?
A. Not that I'm aware of.

Page 179

Q. Have any of Mrs. Hammons' doctors diagnosed -- withdrawn.
Have any of Mrs. Hammons' doctors assessed her to be at risk for future complications because of her PROLIFT® procedure?
A. No.
Q. Do you believe that Mrs. Hammons is at risk for any future complications from her PROLIFT® procedure?
A. No.
Q. Dr. Lowman, I have up on the chart -- up on the screen a chart that we started with Dr. Zipper, and I'd like to go through it with you now, if I could.
A. Okay.
Q. As to the first question, did Mrs. Hammons have a grade 4 bladder prolapse, did you review for the jury today how Mrs. Hammons' physician, Dr. Baker, answered that question?
A. I did.
Q. And did he say she did?

Page 180

A. He did.
Q. Do you agree with Dr. Baker's diagnosis?
A. I do.
Q. As to this question of whether the rectocele and atrophy caused the dyspareunia in 2009, did Dr. Lackey, in his sworn testimony, answer that question?
A. He did.
Q. And what was Dr. Lackey's assessment?
A. Yes.
Q. Do you agree with Dr. Lackey?
A. I do.
Q. As to whether surgical implant technique, as you've more fully described for the jury today, led to the rolling and bunching of the mesh in 2012, did Dr. Heit answer that question?
A. He did.
Q. And what was his assessment, as you understand the record?

Page 181

A. That was his opinion.
Q. Do you agree with Dr. Heit?
A. I do.
Q. As to this question of whether the PROLIFT® was adequately supporting Mrs. Hammons' bladder in August of 2012, did Mrs. Hammons' own physician, Dr. Heit, answer that question?
A. He did.
Q. What is your understanding of the record as to what Dr. Heit, Mrs. Hammons' own doctor, said about that issue?
A. He doesn't indicate any concern for that.
Q. Do you agree with Dr. Heit?
A. I do.
Q. As to the question of whether there are any future complications due to the PROLIFT®, have you seen any indications from any of the records of Mrs. Hammons' doctors that they believe Mrs. Hammons is at risk of

Page 182

future complications from her PROLIFT®?
A. No.
Q. Do you agree with Mrs. Hammons' doctors on that issue?
A. I do.
MR. ISMAIL: Dr. Lowman, I want to thank you for your time, and I appreciate you providing your opinions to the jury.
THE WITNESS: Thank you.
MR. SLATER: Let's go off the record.
VIDEO TECHNICIAN: Off record at 4:46 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 5:02 p.m.
- - -
EXAMINATION
- - -
BY MR. SLATER:

Page 183

Q. Good afternoon, Dr. Lowman.
A. Good evening.
Q. Good evening, you're right. It's the evening now.
Doctor, I want to go over a little bit about your preparation for this deposition, this trial testimony.
Did you have time to prepare for this?
A. I did have time to prepare for this.
Q. How much time did you spend preparing for this testimony?
A. I've been spending the past several weeks preparing to testify. I was made aware, maybe -- I have to -- I'm guessing, but I think it was about two weeks ago of the likely date of the testimony.
It was a last-minute decision to -- not to do that on Friday and to do that today. But I have been preparing over the last several weeks.
Q. How much time would you say

Page 184

you've spent in the past several weeks preparing for this?
A. A significant amount of time. If I had to guess, maybe 40 hours.
Q. Okay. Counsel asked you some questions about your billing rate and the time you've spent. I'd just like to go over that a little bit with you.
A. Okay.
Q. You said that your rate is $400 per hour?
A. Yes.
Q. Actually, your rate is $400 per hour for preparation of your report and review of materials.
But for when you testify, as you're testifying now, we're in a deposition, it's $600 an hour; isn't that true?
A. That's correct.
Q. And you told counsel that you thought you had spent about 100 hours in this case?
A. Yes.

Page 185

Q. When we met, remember we met about a month ago, November 13th, and I was able to ask you some questions?
A. Yes.
Q. At that time, you told us that you had actually had two prior invoices before that time, one for $32,400 and one for $19,600, which was your billing up through October 15th in this matter and maybe one other matter.
A. Yes, that's correct.
Q. And then you told us that -- so let me ask you this: So some portion of that $50,000 was for this case, right?
A. Yes.
Q. What portion?
A. I don't remember. I started evaluating this case first, and then I was asked to evaluate a different case, and then I came back to -- then was asked again to go back to this case. So it's hard for me to say that.
But my best guesstimate of the time that I've spent on this case

Page 186

overall is about 100 hours.
Q. Okay. What I'm asking is this: The $50,000 you had billed for time up through October 15th, you can't give us any idea of how much of that $50,000 was for this case?
A. Not any more than what I just said, no.
Q. Certainly, it would have been at least half or more than half of that, right?
A. No, not necessarily. A great proportion of what I have been reviewing has been the literature. So that's been a significant amount of time, and that relates to all of the cases that I review.
Q. So a significant part of the $50,000 was for reviewing literature?
A. Yes.
Q. Which you've testified about today?
A. Yes.
Q. You told me, when I took

Page 187

your deposition in November, that since October 15th, you had spent over 100 hours in this case at $400 per hour up till the day of the deposition.
Do you remember telling me that?
A. I don't remember that specifically. But that sounds about right.
Q. So as of November 13th, you had spent over -- well, let me take it back.
You had spent some portion of that $50,000 on this case before October 15, right?
A. Yes.
Q. And then after October 15 and up to the day of the deposition, November 13, you had spent over 100 hours more, right?
A. Of the total time.
Q. Well, you told me in the deposition, and I'll have to hand you your transcript here.

Page 188

A. Okay.
Q. Here you go.
If you go to Page 235 of your deposition.
And on Page 235, Line 19, I asked you: Since October 15, do you know how many hours you've spent up through today or, can you estimate, on this case, on Hammons?
And you said: It's been over 100. I don't know exactly.
And the question: Over 100 hours reviewing materials, preparing for the deposition, that sort of thing?
Right.
And then I asked you: And that wouldn't include today?
And you said: That would not include today.
That was the deposition.
And then you were asked, on 236, Line 5: So over 100 hours at $400 an hour on Hammons that you haven't billed for yet?

Page 189

And you said: That's correct.
Right?
A. That's correct.
Q. So as of November 13th, there was over 100 hours at $400 an hour you had not billed for yet through the day before that deposition, right?
A. Right.
Q. And then you did the deposition in November 13th, which was $600 an hour, right?
A. Right.
Q. And then since November 13th and up until today, you've spent at least 40 or more hours? You just told us you prepared for 40 or more hours for this deposition, right?
A. Right.
Q. So that gets us to 100 or so, 140 plus today and the other day of the deposition at $600 an hour, that's all encompassed there, right?
A. Yes.

Page 190

Q. Plus whatever was the portion of the first $50,000, right?
A. Right.
Again, in the beginning of this, I talk about the fact that much of that, before this, was spent on two cases so it was hard for me to be specific.
But in an effort to try to give you a number, that's what I did. And I think that that's fairly accurate.
Q. That was for before October 15th --
A. Yes.
Q. -- when you said you could not tell?
A. Yes.
Q. Right. So you haven't just spent about 100 hours on this case, you've actually spent at least 140 hours, plus the time today and the time in the deposition in November, plus whatever portion of the first $50,000 is for this case, right?
A. That's correct.

Page 191

Q. Now, let's talk a little about your background.
You have no current teaching appointments, right?
A. Right.
Q. You're not a peer reviewer for any medical journal, correct?
A. Correct.
Q. Your publications that you talked about, they were -- they were written when you were still studying as a fellow, correct?
A. That's correct.
Q. And what happened was, you were working under a doctor named Douglass Hale, and he had ideas for some studies he wanted to do and articles he wanted to write, and he would involve his fellows in those projects, right?
A. No. Those studies that I talked about are studies that were my ideas.
Q. The dyspareunia article was your idea?

Page 192

A. That was my idea.
Q. Okay. And the article that we'll talk about, maybe in a few minutes, on the MRI, that was your idea?
A. That was Dr. Hale's idea. It was our idea together, we kind of talked about it together. But the way that the -- the way that study developed over time was more his idea.
Q. And Dr. Hale was an Ethicon consultant for many years and was an Ethicon consultant when you were training with him, correct?
MR. ISMAIL: Objection to foundation.
THE WITNESS: I don't know.
BY MR. SLATER:
Q. You don't know whether he was an Ethicon consultant or was being paid for work?
A. No.
Q. He never told you that?
A. No. Most program directors don't discuss that with their fellows.

Page 193

Q. Now, Dr. Hale, and I'll just show you something we marked as an exhibit, P-1666, that's an abstract presentation of the GYNEMESH®® PS study.
Do you see that?
A. I do.
Q. And do you see who the authors are? It's Dr. Lucente and Dr. Hale, and a couple of other people?
A. Yes.
Q. And were you aware that Dr. Hale was one of the investigators for Ethicon on the GYNEMESH®® PS study?
A. I didn't -- I wasn't aware, no.
Q. Now, let's go and talk about Dr. Lucente a little bit. We've heard his name during the trial.
You know Dr. Lucente, right?
A. I do.
Q. In fact, your residency you did with him?
A. Yes.
Q. Meaning, he was a doctor at

Page 194

the hospital where you were doing your residency?
A. Yes, that's correct.
Q. And he was one of the people that trained you?
A. Yes.
Q. Dr. Lucente, you considered to be a friend, right?
A. I do.
Q. And a colleague, right?
A. Yes.
Q. In fact, you actually called and spoke with Dr. Lucente about this case, didn't you?
A. I did.
Q. And I think what you told us is that when you called Dr. Lucente, you wanted to know, why is it that Dr. Zipper, who had used mesh in the past, is now so against its use; that's what you wanted to talk to Dr. Lucente about, right?
A. Right.
Q. Now, have you seen Dr.

Page 195

Zipper's testimony from the trial?
A. I've seen portions of it.
Q. Portions?
A. Uh-huh.
Q. Do you know that Dr. Zipper said the reason he stopped using the mesh is because of the damage he was seeing to patients and the horrible complications they were suffering?
A. Yes.
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. And you know, of course, there are patients with PROLIFTs® that have suffered very serious, very life-changing complications; you know that, right?
A. There have been patients that have had serious complications, yes.
MR. SLATER: I'm going to need some stickers.
You didn't use any? I'm going to mark them with these when they haven't been marked already.

Page 196

Is that okay?
MR. ISMAIL: That's fine.
- - -
(Whereupon, Exhibit Lowman-1, September 2007 E-mail, was marked for identification.)
- - -
BY MR. SLATER:
Q. Doctor, I'm going to hand you what we marked as Exhibit Lowman-1. And that's an e-mail from September of 2007.
Do you see that?
A. I do.
Q. And, in fact, you can see that Vince Lucente, on September 11, 2007, is writing to somebody, and he's talking about you.
Do you see that?
A. I do.
Q. And he's telling Bart Pattyson, who was a professional education manager at Ethicon, that Dr. Hale's senior fellow, you, was a resident

Page 197

of his and that your loyalty to him was a friction point with Dr. Hale.
Do you see him talking about that?
A. I do.
Q. And is he correct that you have a great deal of loyalty to Dr. Lucente?
MR. ISMAIL: Objection to form.
THE WITNESS: I don't have loyalty to Dr. Lucente. I respect Dr. Lucente.
- - -
(Whereupon, Exhibit Lowman-2, June 2009 E-mail, was marked for identification.)
- - -
BY MR. SLATER:
Q. I'm now going to hand you what we've marked as Exhibit-2. And that's an e-mail in June of 2009.
Do you see that?
A. Yes, I do.

Page 198

Q. And it's written by somebody at Ethicon named Scott Finley, who is a division manager, a sales division manager.
Do you see that?
A. I do.
Q. And he's writing to some people about a program to give professional education to other doctors, and he talks, in the middle, about a proctorship where you and Dr. Lucente would perform a procedure on the PROLIFT®, and other doctors would watch and learn about it.
Do you see that?
A. Yes.
MR. ISMAIL: Objection. Lack of foundation. Give me a minute, Dr. Lowman, to get the objection in.
THE WITNESS: Sorry.
BY MR. SLATER:
Q. You see that that's what's being discussed in the document, correct?

Page 199

MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And you see at the end of the letter, the e-mail that this Scott Finley says that -- they're talking about the targets, people they want to target in connection with this event.
Do you see that?
A. Yes, I do.
Q. And targets, do you know that's language that marketers use at Ethicon when they want to target a doctor to use their products?
A. I do now. I didn't before this trial.
Q. And they're talking about the doctors they want to bring in, and they say, You all need to discuss this program with every mesh doctor in Atlanta, seize the moment and let's conquer.
That's what they were

Page 200

talking about, about this proposed proctorship with you and Dr. Lucente?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: I see that.
BY MR. SLATER:
Q. Now, let's talk about your own background with surgery, okay?
A. Okay.
Q. Tell me if I have my numbers correct.
A. Okay.
Q. You've done about 2,700 total operative procedures for the pelvic floor.
Do I have that right?
A. That's right.
Q. And in those 2,700, you have used mesh in about 1,200 of them?
A. That's correct.
Q. And that includes your fellowship, when you were training in Indiana, and your private practice since then when you finished that in 2008?

Page 201

A. That's correct.
Q. So 1,500 of your operations, more than half, no mesh, correct?
A. That's correct.
Q. And that's for treating pelvic floor?
A. Pelvic floor disorders, yes.
Q. Okay. And now, let's talk about the 1,200 mesh procedures that you have done, including your fellowship and your private practice.
That takes us back to about 2005, right?
A. Right.
Q. So in about ten years?
A. Right.
Q. 1,200 mesh procedures; 150 of them were PROLIFT®, right?
A. Right.
Q. So more than 1,000 of those operations you did something other than the PROLIFT® to treat the person's condition, right?
A. That's correct.

Page 202

Q. And, again, 80 of those were in your fellowship, right?
A. Yes.
Q. So since 2008, after 2008, you only did about 70 PROLIFTs®, right?
A. That's right.
Q. You were using other procedures and other methods to treat prolapse in the other procedures, right?
A. Right.
Q. And for every patient that you treated --
A. Well, all of those procedures weren't prolapse. But for prolapse, I was using other procedures, yes.
Q. When you were doing a prolapse surgery, most of the time you weren't doing a PROLIFT®, you were doing something else, right?
A. Right.
Q. And when you treated a patient and you make recommendations, you try to do a risk/benefit and try to make

Page 203

the best recommendation for the safest, most effective surgery for that patient, right?
A. That's correct.
- - -
(Whereupon, Exhibit Lowman-3, 2010 E-mail, was marked for identification.)
- - -
BY MR. SLATER:
Q. Doctor, I've handed you what we've marked as Exhibit-3. This is an e-mail that goes back to 2010.
Do you see that?
A. Yes, I do.
Q. And I'm actually going to also hand you now Exhibit-4, which is the chart that was accompanying that e-mail when it was sent around within Ethicon.
- - -
(Whereupon, Exhibit Lowman-4, Chart, was marked for identification.)
- - -

Page 204

MR. SLATER: They go together.
BY MR. SLATER:
Q. And if you look at that, you'll see that in the middle of the page -- well, actually, on the second page of this e-mail chain, in February of 2010, someone named Scott Jones, who the jury has met, who is a marketing executive, writes this e-mail. And he's talking about apical support.
Do you see that?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: Yes, I do.
BY MR. SLATER:
Q. Okay. And apical support, that's where there was a recurrence of prolapse with Ms. Hammons, right, at the apex?
A. Yes.
Q. And here, Scott Jones is writing to several people within Ethicon, and says to these people, We need your

Page 205

help to quantify the number of customers that we have lost to a competitive procedure focused on apical support. Our customers continue to tell us they want to see PROLIFT®+M introduced with an anterior apical product code.
And he talks about wanting to present the business case. And he says, a little further down, In the last year we have lost blank number of doctors, which accounted for X procedures. And he wants to be able to talk about the business lost to the company because doctors are telling them we're going to do other things because of lack of apical support.
Do you see that?
A. Right.
MR. ISMAIL: Objection. Lack of foundation.
BY MR. SLATER:
Q. And if you go to the front page of this e-mail, right in the middle of the page, a guy named Robert Zipfel at

Page 206

Ethicon says that, This is a worthwhile effort. Last week at the summit it was clear that our physicians want anterior apical support modification to the PROLIFT®.

Do you see that?

MR. ISMAIL: Objection. Lack of foundation.

THE WITNESS: I do.

BY MR. SLATER:

Q. The attachment to the document, they list doctors and they talk about what product they've converted to.

Do you see that?

A. Uh-huh.

Q. And in the context of doctors stopping using the PROLIFT® because they want to do something else that gives better apical support. They actually list you on that list.

Do you see that?

MR. ISMAIL: Objection. Lack of foundation.

THE WITNESS: I see my name

Page 207

on that list, yes.

BY MR. SLATER:

Q. And they say the product here in 2010 is sacrocolpopexy.

Do you see that?

A. I do.

Q. Sacrocolpopexy is a procedure to treat the apex of the vagina, correct?

A. Yes.

Q. To give apical support, right?

A. Yes.

Q. And, in fact, that's your go-to procedure for apical support, you feel that that's a terrific procedure and very safe and effective, right?

A. It's -- yes.

Q. And do you agree or dispute that you stopped using the PROLIFT®, whether at this point or another point, and converted primarily to sacrocolpopexy on procedures where you may have considered the PROLIFT®?

Page 208

MR. ISMAIL: Objection to that question. Violates motion limine and agreement of the parties.

THE WITNESS: I disagree with that assessment.

BY MR. SLATER:

Q. So the document is incorrect from --

A. The document is incorrect. Sacrocolpopexy is Dr. Hale's bread and butter. That's what we were trained to do more than anything else. So sacrocolpopexy has always been my go-to.

Q. Sacrocolpopexy was -- has always been your go-to in your private practice, right?

A. It has.

Q. The PROLIFT® was never your go-to, right?

A. When you say "go-to," the most commonly performed procedure, if that's what you mean, yes, that's correct.

Page 209

Q. Let's just talk about when you stopped using the PROLIFT® so we're oriented.

You told me in the deposition you weren't sure about when, but it would be at least three years, three and-a-half years ago, right?

MR. ISMAIL: Objection. Violates motion limine.

THE WITNESS: Approximately three years ago, yes.

BY MR. SLATER:

Q. You haven't done a PROLIFT® in over three years, so that's 70 PROLIFTs® in maybe five years, right?

MR. ISMAIL: Objection. Violates motion limine and agreement.

THE WITNESS: I think that's right.

BY MR. SLATER:

Q. I'd like to talk a little bit with you about your role as an expert, if we could.

Page 210

A. Okay.
Q. And as an expert, you're essentially brought in, and you're supposed to be objective and look at the important evidence and render opinions, right?
A. That's correct.
Q. And it's very important, in order to do a full investigation and give a valid opinion to know the important evidence, right?
A. Right.
Q. One of the things you want to do as an expert, or should want to do, is see the important evidence, right?
A. Yes.
Q. You want to have the most complete information possible, correct?
A. The relevant information, yes.
Q. For example, you would want to at least know and consider the information the jury has been presented and that the jury may feel is important;

Page 211

you'd want to at least take that into account, right?
MR. ISMAIL: Objection.
THE WITNESS: Would I, as an expert, want to know what the jury has taken into account? Not -- no. I don't think that's relevant to the -- evaluating the case, what the jury knows.
BY MR. SLATER:
Q. Your opinions are based on the information you have available to you, right?
A. Yes.
Q. If there's information the jury thinks is important, they've seen the case now for a few weeks, and you haven't considered that information, the jury would be within its rights to reject your opinions because you're not considering factual information they think is important, correct?
MR. ISMAIL: Objection.
THE WITNESS: No. I'm

Page 212

giving opinions about the case, not about what's being presented to the jury.
BY MR. SLATER:
Q. Is it important that you understand the PROLIFT®?
A. Yes.
Q. Is it important that you understand and know the complications caused by the PROLIFT®?
A. Yes.
Q. Now, you wrote a report which is about 58 pages long, right?
A. I did.
Q. And I think you told me before, that had all the important information and facts in it, right?
A. I said it had most of the important information and facts, yes.
Q. You seem like a careful person.
Did you carefully write the report?
A. I did.

Page 213

Q. Did you proofread it, make sure it said exactly what you wanted it to say?
A. I did.
Q. And if you could, turn to Page 17 of the report.
MR. ISMAIL: You'll have to give it to her.
MR. SLATER: Oh, I'm sorry. Sorry about that.
BY MR. SLATER:
Q. Okay, Doctor, this is your report in front of you, correct?
A. Yes, it is.
Q. And, you know what, maybe what I should do is put a sticker on it.
- - -
(Whereupon, Exhibit Lowman-5, Expert Report of J. Lowman, M.D., was marked for identification.)
- - -
BY MR. SLATER:
Q. I'm sorry, every piece of

Page 214

paper gets a sticker. Sorry about that. Let's start again.

Exhibit-5 that I've just given you, is that a copy of your report in this case?

A. Yes.

Q. And that's the report you just told us you carefully wrote and carefully proofread so it said exactly what you wanted it to say?

A. Yes.

Q. If you look at Page 17, you're talking about your personal experience with the PROLIFT® and that started during your fellowship?

A. Yes.

Q. And if you go about halfway or more down that paragraph, you talk about it looks very intricate and complex at first.

Do you see that sentence?

A. I do.

Q. The large mesh with eight arms laid out on the slides looked

Page 215

ominous, right?

A. Right.

Q. And you stand by that statement, right?

A. Well, it's six arms.

Q. Okay. So when you wrote this report, you said it was eight arms on the PROLIFT® when it's really only six arms, right?

A. That's correct. I made an error. I am human.

Q. Now, Doctor, have you had the opportunity to know what testimony has been given during this trial?

You said you knew a little bit about Dr. Zipper. Is that it?

A. That's pretty much it, yes.

Q. Okay. Now, I want to ask you another question about the PROLIFT®. And I want to understand what you know about what the mesh does in the human body, if we could for a few minutes, okay?

A. Okay.

Page 216

Q. Do you agree with me that the PROLIFT® causes a chronic inflammatory reaction?

A. It does cause some -- any foreign body is going to cause an inflammatory reaction. Whether or not it's chronic or not, I can't testify to that.

Q. Is it because you don't know?

A. It's not that I don't know, I just haven't seen that documented in the literature as it relates to the PROLIFT®.

Q. Are you aware that there can be a chronic inflammatory reaction to the PROLIFT® mesh that can be, in some women, severe?

A. I'm aware that there is inflammation associated with the mesh, as it is with any foreign body. I haven't read any evidence that suggests that that inflammation is what causes difficulty or complications with the mesh.

Page 217

Q. We're going to come back to that in a couple of minutes.

I want to go through a little bit of your background, in terms of what materials you reviewed in this case, okay?

A. Okay.

Q. And then we'll come back to that question in a little bit.

A. Okay.

Q. Did you assume that if there was something important, either an Ethicon document or testimony by an Ethicon witness, that the lawyers that represent Ethicon would have given that to you to consider?

A. Testimony by whom? Could you repeat the question?

Q. If there was important evidence, either in a document or in a deposition from people who work at Ethicon, who worked with the PROLIFT® and know a lot about it, would you assume that if there was important information

Page 218

from those types of people, that the lawyers representing Ethicon would have given that to you?
A. Not necessarily.
Q. Did you have interest in knowing what the people who actually developed and were responsible for the safety of the PROLIFT® had to say about it?
A. I was interested in reading the -- about the development by the Jacquetin and Cosson, who helped to develop the product, yes.
So as it relates to what's published in the scientific literature, I was very interested in that.
In terms of what employees at Ethicon thought about it, that's less relevant.
Q. Let's talk about some people, and I want to ask you a few questions.
A. Okay.
Q. Do you know who Charlotte

Page 219

Owens is?
A. I don't.
Q. Do you know who David Robinson is?
A. That name sounds familiar, but I can't say specifically who he is.
Q. Do you know who Piet Hinoul is?
A. No.
Q. Do you know who Scott Ciarrocca is?
A. No.
Q. Do you know who Paul Parisi is?
A. No.
Q. Do you know who Price Saint Pallere is?
A. No.
Q. Do you know who Axalar Noh is?
A. I've seen his name mentioned a lot in the depositions, but I don't know who he is.
Q. You don't know anything

Page 220

about what he does or anything like that, right?
A. I don't.
Q. Do you know who Dr. Jim Hart is?
A. No.
Q. Do you know who Scott Jones is?
A. No.
Q. We did just go through his e-mail. In fairness, he's a marketing executive.
But you didn't know that until I showed you that?
A. Right.
Q. Am I correct that you still don't even know who those people are now, including Scott Ciarrocca, who testified in court before this jury?
MR. ISMAIL: Objection.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. You haven't had the chance

Page 221

to see the testimony he gave? You have no knowledge about that?
A. I haven't tried to look at the testimony he gave.
Q. Whatever he said in court is irrelevant to you, fair?
A. That's fair.
Q. There's nothing that Scott Ciarrocca could have said that would have any impact on your opinions, right?
MR. ISMAIL: Objection.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. In fact, there's nothing that I could show you that any of those people I just listed said that could have any impact on your opinions, correct?
A. That's correct.
Q. In fact, you didn't read the deposition of any witness employed by Ethicon at all; is that true?
A. That would be true.
Q. Let's go through a little

Page 222

more information.
Do you know what Ethicon medical affairs is? Do you know what that department is?
A. I don't.
Q. Do you know the background or the qualifications of any of the medical affairs directors?
A. No.
Q. Do you know whether their surgeons, who are urogynecologist in private practice before they joined Ethicon?
A. I don't know that.
Q. Do you know if some of them were investigators and did clinical studies on the PROLIFT®?
A. I did not know that.
Q. You mentioned a few moments ago Dr. Jacquetin and Dr. Cosson.
Their literature is important information, right?
A. Yes.
Q. The things that they know

Page 223

about the PROLIFT® and the PROLIFT® mesh, that's important to you because they developed this procedure, right?
A. Yes. And because they've published in peer-reviewed literature.
Q. You don't know what Professor Jacquetin and Dr. Cosson were telling Ethicon about the mesh privately, do you?
A. I don't.
Q. So you know what they published, but you don't know what they were saying privately?
A. That's correct.
Q. Is it of any significance to you to know what Jacquetin and Cosson were telling Ethicon privately, for example, in e-mails and conversations?
MR. ISMAIL: Objection.
THE WITNESS: No.
BY MR. SLATER:
Q. If the jury has seen evidence and heard evidence that Jacquetin and Cosson were asking Ethicon

Page 224

for a new, safer mesh to be used in the PROLIFT®, would that have any significance to you at all?
MR. ISMAIL: Objection.
THE WITNESS: No, not in formulating these opinions. No.
BY MR. SLATER:
Q. Do you know what Ethicon did to evaluate the safety of the PROLIFT® before they put it on the market to be put in women's bodies all over the United States and the world?
A. I don't know what Ethicon did, but --
Q. That's what I'm asking.
A. No.
Q. Do you know what Ethicon did to evaluate the safety of the PROLIFT® once it was on the market?
A. I know that they were involved in funding some of the research that was done.
Q. Do you know who at Ethicon was evaluating the research that was

Page 225

being done?
A. I don't.
Q. Do you know if there were people at Ethicon that would read reports of people being harmed by the PROLIFT® and consider that? Do you know if that would go on?
MR. ISMAIL: Objection.
Calls for speculation.
THE WITNESS: I don't.
BY MR. SLATER:
Q. Is it fair to say that whether or not Ethicon was evaluating the safety of the PROLIFT® or not or how they did it is really not of any interest to you?
MR. ISMAIL: Objection.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. Did you make any effort to learn what information Ethicon had compiled internally regarding the safety or efficacy of the PROLIFT®?

Page 226

A. No, I did not.
Q. That wouldn't have been any -- of any significance to you, right?
A. No.
Q. Let's go through a few more terms, just to kind of clear off my checklist if we could.
Do you know what design control is?
A. No.
Q. Do you know what a design requirements matrix is?
A. No.
Q. Do you know what an FMEA is?
A. No.
Q. Do you know what a DDSA is?
A. No.
Q. Do you know what an Ethicon clinical expert report is?
A. No.
Q. And all these things I've asked you about that you say you're not familiar with, to be fair, that's -- you didn't consider any of those things in

Page 227

forming your opinions, right?
A. That's correct.
Q. Do you know anything about what criteria or standards Ethicon applied when deciding to put the PROLIFT® on the market?
A. No.
Q. That would not be of any significance to you, right?
MR. ISMAIL: Objection to form.
BY MR. SLATER:
Q. Is that correct?
A. That's correct.
Q. Other than what's published in the literature, you don't know what Ethicon knew about the risk/benefit profile for the PROLIFT®, correct?
A. That's correct.
Q. And what Ethicon internally knew about the risk/benefit profile of the PROLIFT® is not of any importance at all to you, correct?
MR. ISMAIL: Objection.

Page 228

THE WITNESS: No.
BY MR. SLATER:
Q. Meaning --
A. Yes, you're correct.
Q. That's okay.
Now, coming back to my question about the inflammatory response, I'm going to show you something that we're going to mark as Exhibit-6, which is the testimony of Charlotte Owens that was submitted to the jury. This is a transcript of that.
- - -
(Whereupon, Exhibit Lowman-6, Excerpt of Testimony of C. Owens, was marked for identification.)
- - -
THE WITNESS: Okay.
BY MR. SLATER:
Q. And if you look, there's what we call numbered clips. And if you go to clip 36, there's some questions and answers of Charlotte Owens, who you told

Page 229

us you don't know who she is. But let's look at what she said.
A. Where do I find the clip numbers?
Q. It's Page 8. The bottom right --
A. Oh, Page 8.
Q. -- there's page numbers. Sorry about that.
A. Uh-huh.
Okay.
Q. And you can look at that and you can read it to yourself so I don't have to read it out loud, and then I'll just ask you a question about it real quick.
Actually, to save time, let me read it. She was asked, on Page 273, Line 25: You also understood that there were some women that would generate a more severe inflammatory reaction that would not be minimum or slight and which would not be transient but would be chronic, correct?

Page 230

And she then testifies:
This statement is about what we saw in our animal studies, but what you state is also a possibility. But this statement is about what we demonstrated in our animal studies.
And then she was asked:
What I stated just a moment ago, you understood that that would occur in some women, correct?
And she says: That can occur in some women.
Do you see that?
A. I see that.
Q. Now, I'll just let you know, Charlotte Owens is the medical director who signed off to let the PROLIFT® go on the market.
You didn't know that before I just told you that?
A. No.
Q. And she testified that the inflammatory reaction is chronic and can be severe.

Page 231

You see that, right?
A. Yes.
Q. Does that have any impact on your opinions in this case?
A. No.
Q. Because, again, I think you told me there's really nothing that I could show you that would change your opinions, correct?
MR. ISMAIL: Objection. Asked and answered.
THE WITNESS: Do I answer it or not?
MR. ISMAIL: Yes.
THE WITNESS: That's correct. Because, as I said before, I focus my clinical decision-making on peer-reviewed literature.
BY MR. SLATER:
Q. When you say you focus your clinical decision-making, you're talking about what you do in your practice and what you did in your practice, right?

Page 232

A. That's correct.
Q. And when you've --
A. And my opinions in general.
Q. Right. But when you're talking here as an expert, you're basing that on your own experience and the medical literature, right?
A. That's correct.
Q. And you're basing it, when you're talking about your experience, on what you do in your practice and what you've done in your practice, right?
A. That's right.
Q. Let's talk a little bit now about some medical literature, because you just talked about that a bit.
A. Okay.
Q. I'm going to hand you an article that was marked as PLT 352.
And this is an abstract, on the right-hand side, that was published in the Journal of Pelvic Medicine and Surgery, in March and April 2006.
Do you see that?

Page 233

A. Uh-huh.
Q. And you see who the authors are, it includes Vince Lucente and Miles Murphy, and the doctors he works with at his practice?
A. Yes.
Q. And is this the type of literature you did rely on in forming your opinions?
A. No. I relied on the highest levels of evidence. Smaller studies were considered; I mean, I did review them and read them. But what I relied on was the highest levels of evidence that we described a few moments ago.
Q. When you say "the highest levels of evidence," are you saying you only relied on randomized control trials?
A. No. What I'm saying is I rely most heavily on those -- on those studies, because they have -- the strength is better of those studies.
Q. Well, this article, for example, and I think you told me in your

Page 234

deposition, one of the things you relied on, in forming your opinions, was Dr. Lucente's literature; is that true?
A. All of the literature, yes.
Q. So this is one part of his literature, correct?
A. This is.
Q. And you see it was 89 patients, right?
A. Yes.
Q. And then if you go down into the results section, about halfway down, they say that, Of the 89 patients, there was one mesh -- erosion of mesh into the bladder and this was the only erosion.
Do you see that?
A. I don't see that yet.
Q. Go down about two-thirds of the way.
A. Two-thirds of the way.
Okay.
Q. There was an erosion of mesh into the bladder, and this was the only erosion, one out of 89 patients.

Page 235

Do you see that?
A. Are you on the first page?
Q. Yes.
A. I don't see it yet.
Q. If you go down the results section, about halfway down.
A. Yes.
Q. Now, let me give you another article that we marked as PLT 485.
This is an article about the PROLIFT® written by Dr. Lucente's group again.
Do you see this?
A. Yes.
Q. Published in the American Journal of Obstetrics and Gynecology in 2008?
A. Yes.
Q. And if you turn to the second page of the article, it's Page E2, in the results section, there's a paragraph that goes over to the third column.
And at the very bottom of

Page 236

that column, it says, No mesh exposures or erosions were detected.
Do you see that?
A. I see that.
Q. And if you look just to the left of that, in the results section, it says that, There were 97 patients that came back for their one-year visit.
Do you see that?
A. Yes.
Q. So this is 97 patients they're reporting on, no exposures or erosions. Vince Lucente and his group, right?
A. Yes.
Q. And, again, this is the type of article that you took into account in forming your opinions, right?
A. Yes.
Q. And when Vince Lucente -- let's get to the next one, actually. I'll give you a third article, it's P-1500.
And this is a manuscript

Page 237

written by Dr. Lucente and his group regarding results of the PROLIFT® with 349 patients.
Do you see that?
A. Yes.
Q. And if you go to the second page, there's an abstract. And at the very end of the results section of the abstract, on the second page it says, Mesh exposure was seen in four, 1.1 percent of the patients.
So four out of 349.
Do you see that?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: I see that.
BY MR. SLATER:
Q. So this literature, again, is Dr. Lucente. And this was, again, the type of thing you relied on, correct?
A. This is the type of study that I would rely on, yes.
Q. And you're comfortable with Dr. Lucente and his group reporting in

Page 238

one study of 89 patients, one erosion into the bladder; 97 patients with no erosions; and then 349 patients where there was only a 1 percent exposure rate? You're comfortable with that data?
A. Yes, I'm comfortable with that.
Q. You believe that?
A. I have no reason not to believe it.
Q. Do you know what Ethicon thinks about that?
MR. ISMAIL: Objection.
THE WITNESS: No.
BY MR. SLATER:
Q. Is it your testimony for this jury that those erosion rates are credible and believable?
A. Yes.
Q. Doctor, I'm going to hand you now what we've marked as PLT 0302.
And that's the article you told the jury about that you were one of the authors of?

Page 239

A. Yes.
Q. And the question is, Does the PROLIFT® System Cause Dyspareunia? That's the question at the top of the article?
A. Right.
Q. The answer to that question is yes, right?
A. No.
Q. You're saying the PROLIFT® doesn't cause dyspareunia?
A. No, it doesn't. It's associated with a risk of de novo dyspareunia in the same way that all of the procedures are.
Q. Is it your testimony that the PROLIFT® system and the PROLIFT® mesh doesn't cause dyspareunia in any women?
A. It -- that's not my testimony. My testimony is that the dyspareunia can be associated with that surgery, in the same way that it's associated with any procedure that we do.
And I described why patients

Page 240

who have surgery then have dyspareunia afterwards. It's not just using the product, but it's also the fact that we've made an incision at the time of surgery and everything else that I've previously discussed.
So I think to say that the PROLIFT® causes dyspareunia is an overstatement.
Q. You're not testifying to this jury that every woman who has surgery for pelvic organ prolapse, whatever the procedure is, ends up with dyspareunia, are you?
A. I'm not, no.
Q. Women will have some discomfort when they're healing from the surgery, that's true across the board, right, because they have an incision in the vagina that has to heal, right?
A. Right.
Q. And for most women, that heals up and they're okay after that, right?

Page 241

A. Right.
Q. For some women, they have a PROLIFT® and due to the PROLIFT®, the mesh and the impact of the PROLIFT® mesh on their body, they get dyspareunia; that happens to some women, right?
A. I think that that's a misstatement. Just as we've talked about, women that don't have mesh and don't have PROLIFTs® also end up with dyspareunia after surgery.
Dyspareunia after surgery is multifactorial. So I think it's a misstatement to say that the PROLIFT® causes dyspareunia.
Q. In some women, you would agree the PROLIFT® causes dyspareunia, right?
A. No, I don't think that we can say that, for the reasons that I have just discussed.
Q. The jury has heard testimony, and let me just give it to you to be fair.

Page 242

- - -
(Whereupon, Exhibit Lowman-7, Excerpt of Testimony of P. Hinoul, was marked for identification.)
- - -

BY MR. SLATER:

Q. We marked this as Exhibit 7. This is the testimony the jury heard from Piet Hinoul.

You said you don't know who he is, right?

A. Right.

Q. Just in fairness, Piet Hinoul is the worldwide medical director at Ethicon. He's a urogynecologist who was trained by Professor Cosson on how to do the PROLIFT®.

A. Okay.

Q. And works at Ethicon as their designated corporate representative for medical affairs.

A. Okay.

Q. Just so you know who he is.

Page 243

And if you could turn in this exhibit to the third -- to the fourth page, please.

And he's talking there about some of the risks --

A. It says -- it's numbered 1, 2, 3 and then 1 again.

Q. Don't -- if you just go to the fourth page, the fourth page is actually a new Page 1 because that's testimony from an April 6th, 2012, deposition. You see at the top, that date.

A. Yes, okay.

Q. No problem.

So here Dr. Hinoul, who is the worldwide medical director for Ethicon, is asked: You knew that significant retraction would occur -- could occur?

He says: Right.

Do you see that?

MR. ISMAIL: Objection. Lack of foundation.

Page 244

THE WITNESS: I see that, yes.

BY MR. SLATER:

Q. And if you go a little further down -- let me start over. I'm going to start over.

Dr. Hinoul here is testifying about the PROLIFT®. And do you see on Line 22, Page 382, Line 22, he's talking about the PROLIFT® and he's asked: You knew it could lead to dyspareunia?

And his answer is: Yes.

Do you see that?

MR. ISMAIL: Objection. Lack of foundation.

THE WITNESS: Yes.

BY MR. SLATER:

Q. And this is testimony the jury has already seen, in fairness. You don't know that. You're seeing this for the first time?

MR. ISMAIL: Objection. Lack of foundation.

Page 245

THE WITNESS: I'm seeing this for the first time.

BY MR. SLATER:

Q. Do you disagree with Piet Hinoul, who is a urogynecologist, who was trained by the inventor of the PROLIFT® and was in charge of overseeing the PROLIFT® for years at Ethicon? Do you disagree with his testimony to the jury?

A. I think that's an overstatement, yes.

Q. So you disagree with Piet Hinoul?

MR. ISMAIL: Objection.

THE WITNESS: Yes.

BY MR. SLATER:

Q. And if we were to show you internal documents where Ethicon acknowledged that the PROLIFT® could cause dyspareunia, you would disagree with every one of those documents, right?

MR. ISMAIL: Objection.

THE WITNESS: I would disagree with that assessment,

Page 246

yes.
BY MR. SLATER:
Q. Now, in your article, which we have here, PLT 0302, there was a 16 -- actually, you called it a 17 percent de novo dyspareunia rate.
That's what you reported in this article, correct?
A. That's correct.
Q. De novo dyspareunia means the person didn't have any discomfort with sexual relations before the surgery, after the surgery the woman has discomfort with sexual relations, right?
A. That's right.
Q. And 17 percent of those women that had no discomfort to begin with ended up with it after, that's what you've documented, right?
A. 17 percent of the patients that were currently sexually active, yes.
Q. Now, you had previously submitted an abstract of this study where you had quoted a 24 percent de novo

Page 247

dyspareunia rate, correct?
A. Yes, I believe so. Do you have that for me?
Q. Sure. PLT 1096.
A. Thank you.
Q. That's the abstract for the same article where you previously, in March and April of 2008, reported 24 percent new dyspareunia for patients with the PROLIFT®, right?
A. Yes, that's right.
Q. Now, whether the rate is 16 or 17 percent or 24 percent, those are high rates of dyspareunia, correct?
A. Correct.
Q. Now, if you look at your article, and you turn into the article several pages, you actually have a calculation or the numbers of patients that were counted for this study, right? To determine that 17 percent, right?
A. Where are you talking about?
Q. In your article.
A. Right. But where in the

Page 248

article?
Q. I think it's on Page E3 or E4. Let's turn to that. Here we go. It's actually Page E2 into E3.
What you're talking about there is you sent questionnaires out to these patients, validated questionnaires, right?
A. That's right. One of them was validated, one was not.
Q. A validated questionnaire is something that the urogynecology community of doctors has said, okay, these questions are valid to find out if somebody has dyspareunia in this case, right?
A. No. It's a validation of sexual -- in this case, it would be a validation of whether or not that questionnaire accurately captures or assesses sexual function.
It's not -- PISQ -- the PISQ 12 is not specific for dyspareunia, which is why we included that non-validated

Page 249

questionnaire, because that was specific for dyspareunia.
Q. You created your own questionnaire to accompany the validated one so you would get really good questionnaire data, right?
A. That's right. More comprehensive data about dyspareunia.
Q. Now, if you take the number of people that answered the questionnaires, and we go through it, this is on Page E2 in the right-hand column, it says that 56 patients agreed to answer the questionnaires and 41 of them actually answered it, right?
Right-hand column, under the results, first full -- second paragraph.
A. Yes.
Q. So we have -- so we have 41 women that we're now studying through the questionnaires because that's how many answered it?
A. Right.
Q. And so we have 41 total.

Page 250

And then if you go down through it, they talk about -- or you talk about, on the next page -- let me just find it -- it's right there underneath. Sorry. Let's start over.

Right underneath the 41 patients, it says, 20 of the 41 sexually active patients who responded to the questionnaires described themselves as pain free.

Right?

A. Right.

Q. So 20 are okay, and that leaves 21 with dyspareunia, correct?

A. I think that's correct.

Q. Okay. Then if you go to the next page, the top of the left-hand column, the first full paragraph, Page E3, it says, 8 of the women reported having dyspareunia at baseline.

Eight of the 41, right?

A. Yes.

Q. So you would want to subtract those both out of the numerator

Page 251

and denominator, because you're not going to find out if someone has new dyspareunia if they had it to begin with, correct?

A. That's correct.

Q. So right now we have 21 women who ended up with dyspareunia after the surgery out of a total of 41, so we have to subtract those eight women from both sides so it's appropriate, right?

A. Let me think about that.

Q. You have 21 women with dyspareunia after the surgery, you want to take out the eight that had it before?

A. Well, this is retrospective self-report.

Q. I understand that. We're just doing math.

A. So we don't have -- we don't have a denominator on the number of patients that were sexually active total. This is just by retrospective self-report.

So the only thing that I can

Page 252

say is that 13 were saying that they had de novo dyspareunia, meaning that they answered the first question, which was, do you have pain with intercourse, as a yes; and answered the second question, did you have pain with intercourse before surgery, as a no.

I don't know the total denominator. I just have to use those numbers objectively.

Q. I'm using the numbers in your article.

A. Okay.

Q. And the numbers in your article are, you have 21 women with dyspareunia after the surgery, right?

Remember, we went through, and it says 20 of the women said they were okay, they didn't have dyspareunia.

So it leaves 21 women with dyspareunia, right?

A. Okay.

Q. So we have 21 women with dyspareunia.

Page 253

If you subtract the eight that had it to begin, with that leaves you 13, right?

A. Right.

Q. If you subtract them from the numerator, the top, you also subtract it from the denominator, right?

MR. ISMAIL: Objections.

THE WITNESS: No, what I'm saying is, there's no denominator.

BY MR. SLATER:

Q. I'm asking --

A. No, that's not right.

Q. Well, we're using 41, that's the entire group of women that answered the questionnaires, right?

A. Right.

Q. So let's just stick with the 41 women that we actually have data on here, questionnaires.

If you subtract the eight women from the 21, because they had it to begin with, you also subtract them from the total of 41, right?

Page 254

MR. ISMAIL: Objection.
BY MR. SLATER:
Q. So that the calculation will be accurate?
MR. ISMAIL: Objection.
Asked and answered.
THE WITNESS: I don't think that's right.
BY MR. SLATER:
Q. Well, let's do this. You have eight women that had dyspareunia to begin with, right?
A. Yes, by retrospective self-report. Yes.
Q. So you're not going to want to evaluate them for whether they had dyspareunia or not after because we know they already had it, and you're looking to find new dyspareunia, right?
A. Right.
Q. So if we subtract them out of the 41 total, that goes to a total of 33 women that didn't have dyspareunia to begin with, right?

Page 255

MR. ISMAIL: Objection.
THE WITNESS: No. Because the eight women aren't in the same group as the 41 women. There's a total of -- there's a total of -- how many patients answered this? 56 patients answered --
BY MR. SLATER:
Q. There's actually 41.
A. So 41 patients answered the questionnaire. Right. Okay. Forty-one patients answered the questionnaire. Out of those 41 patients, eight said that they had de novo dyspareunia. So eight said that they had dyspareunia --
Q. No, eight said they had dyspareunia at baseline in the beginning. That's what you said right here.
A. Okay. Eight said that they --
Q. Do you see that at the top of the left column on Page E3.
Eight reported dyspareunia as baseline, leaving 13 with de novo

Page 256

dyspareunia --
A. Where are you?
Q. -- by retrospective self report?
First full paragraph on E3, first sentence.
A. I'm on E3. Eight respondents reported dyspareunia at baseline, leaving 13 with de novo dyspareunia by retrospective report.
Right.
So the baseline, the 13 is, I believe, the number of patients that had dyspareunia, and out of those 13, eight of them described it as de novo.
Q. That's not what you say there. You say, eight respondents reported dyspareunia at baseline, leaving 13 with de novo dyspareunia.
So it's 21 minus eight equals 13, right?
A. Right.
Q. So that's how you get the number of women out of the 41 that had

Page 257

dyspareunia only after the PROLIFT®, right?
A. Right. By retrospective self-report.
Q. Right.
A. So it's a proportion of that 41 patients. It's not -- the denominator is not 41. When you're looking at -- this -- I don't -- we can go on about this.
But what I'm trying to say is that when you look at the questionnaires, the only thing that I can say is what proportion of those patients have dyspareunia. It's not whether or not they developed de novo dyspareunia from baseline, because I don't have that baseline data. These were anonymous questionnaires.
The only way that I can -- that I can estimate or calculate a de novo dyspareunia rate objectively from all of the patients that were sexually active is to know who was answering the

Page 258

questions.
So what I'm reporting is a proportion of patients who are reporting that they felt de novo dyspareunia.
I don't know how else to say it. But it's different from what you're saying.
MR. SLATER: Move to strike as nonresponsive.
BY MR. SLATER:
Q. Doctor, in your abstract where you reported 24 percent, you base that on the questionnaires plus talking to the people on the phone, right?
A. Right.
Q. And then when you did your article, you had 41 women who responded to the questionnaires, correct?
A. Correct.
Q. Of those, 21 had dyspareunia after the PROLIFT®, right?
A. Of those that responded to the questionnaires?
Q. Yes.

Page 259

A. Ask the question again.
Q. Of the women who responded to the questionnaires, we only have 41 women, that's the number you can study, right, based on --
A. Right.
Q. -- the questionnaires, because that's what you have, right?
A. Right.
Q. So you have, of the 41, 20 were okay and 21 had dyspareunia after the surgery, right?
A. Right.
Q. So that's 21 out of 41, right?
A. Right.
Q. But eight of those 21 women had dyspareunia, according to their questionnaire results, before the PROLIFT®, right?
A. Right.
Q. Since you're studying women who have new dyspareunia, you don't want to count them because it's not new in

Page 260

their case, right?
A. Right.
Q. So you subtract them out of the calculation, if you just want to find the percentage of the 41 that had new dyspareunia, correct?
A. Right.
Q. And that would leave you 13 women with new dyspareunia out of 33, which was the total that didn't have it before, correct?
A. No.
Q. There were 41 women total who answered?
A. This is the thing --
Q. Doctor --
A. -- we didn't calculate --
Q. Doctor --
A. -- the rate of de novo dyspareunia based on the questionnaires. We calculated the rate of de novo dyspareunia based on chart review and telephone interview.
The questionnaires was

Page 261

simply an effort to try to get more information about dyspareunia and how they were experiencing it, whether or not it was mild, moderate or severe; when they were experiencing it, with deep penetration, et cetera.
We did not use the questionnaires, nor were the questionnaires designed to assess a rate of de novo dyspareunia. You can't do that, if you don't know who is answering the questionnaires. Because I don't know what their baseline incidence of dyspareunia was.
The only reason we asked the questions on the questionnaire was to then be able to relate their answers on the questionnaire to whether or not they, by self-report, had de novo dyspareunia.
So the objective assessment of dyspareunia is different from a patient's self-recollection of dyspareunia. Are the numbers different? If you want to say that, that's fine.

Page 262

But we're assessing two different things with those two different evaluations.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Dr. Lowman, what I want to do is just go through a little bit of the calculation, and we went through this at your deposition, remember?
A. Right.
Q. All I'm trying to do is figure out the percentage of those 41 women that reported de novo dyspareunia, okay?
A. Okay.
Q. It's all I want to do right now.
A. Okay.
Q. So if we go through it very simply, 41 women answered the questionnaires, right?
We've established that? 41 women answered the questionnaires?
A. 41 women answered the questionnaires.

Page 263

Q. 21 said they had dyspareunia after the PROLIFT® surgery, right?
A. Yes.
Q. So 21 out of 41, correct?
A. 21 out of 41, yes.
Q. Eight of those 21 women had it to begin with, before the surgery; so you can't study them for new dyspareunia because they already had it, right?
A. You can't study any of these respondents for de novo dyspareunia.
MR. SLATER: Move to strike.
THE WITNESS: That's what I'm trying to tell you. I don't know what their baseline dyspareunia rate was, objectively. When you're studying something, an objective outcome, you have to study that objectively.
That's -- I can't tell who had de novo dyspareunia or not, based on a retrospective questionnaire that's anonymous.
MR. SLATER: Move to strike.

Page 264

BY MR. SLATER:
Q. Doctor, I just want to go through what the information is that you reported here in --
A. I'm trying to get through that.
Q. We'll get to what you want to talk about, we both want to talk about.
A. We're talking about what you want to talk about.
Q. We're not. I just want to do a calculation.
A. Okay.
Q. I just want to do is math.
A. Okay.
Q. All I want to do is math.
A. Okay.
Q. So let's start again, and just try to go through the numbers.
A. Okay.
Q. Doctor, 41 --
A. Can I have a pen to go through the numbers with --

Page 265

Q. Sure.
A. And let me just read it again. Can I have a sheet of paper?
Q. I have some paper for you, Doctor. Here is a piece of paper.
A. Give me a minute to read it.
Q. Doctor, in the interest of time, what I'd like to do is go to the transcript of your deposition, and we'll just walk through the transcript, okay?
A. To answer any more questions about this, I need to read this again. So if you could just give me a minute and let me read it again.
Okay.
Q. And, Doctor, what I'd like to do, you have your deposition transcript, I gave it to you before. Let's go to Page 173 of your deposition transcript.
A. I can answer your question now, without that, if you'd like.
Q. This is what I'd like to do, Doctor, in your article, you say that you

Page 266

sent questionnaires out to 56 women and 41 responded, correct?
A. That's correct.
Q. And those questionnaires were designed to determine how many women, or what percentage of women were reporting or had new dyspareunia after the surgery, correct?
A. No. That's what I'm saying. That's not what the questionnaires were for.
The questionnaires were sent out to get greater -- get greater information about the quality of their dyspareunia, how severe it was, where they were experiencing it, and if the dyspareunia was so bad that they wouldn't have the procedure done again.
Q. Doctor, when you reported the results of this study in the abstract I gave you as PLT 1096, you reported a 24 percent dyspareunia rate, new dyspareunia, based on the questionnaires, correct?

Page 267

A. I have to look at that.
No, we didn't -- we didn't assess the rate of de novo dyspareunia based on the questionnaires.
Q. That's what it says, though?
A. Where does it say that?
Q. Right in the results section, 49 were currently sexually active and were mailed questionnaires?
A. Right.
Q. 33 patients responded; 7 of the 33 who responded had dyspareunia preoperatively; 8, 24 percent, developed de novo dyspareunia.
And that's the figure you reported. The 8 -- 24 percent per the questionnaires, that's what you reported, correct?
A. Right.
Q. It's a simple yes or no. I just want to know --
A. We reported --
Q. Doctor, I just want to know --

Page 268

A. -- what we had at the time.
When we presented this data, it was abstract. That means the -- the study is still ongoing. An abstract is what we submit to whatever body it is that we're submitting it to, to present our data, about what we currently have. It's not final data.
There were several patients in this cohort of patients who had just had surgery and were not yet sexually active. We were still evaluating the data.
Did we ask the question, do you have de novo dyspareunia from the questionnaires? Yes. Did we assess de novo -- de novo dyspareunia rate by questionnaire? No.
MR SLATER: Move to strike.
BY MR SLATER:
Q. The data reported in the Journal of Pelvic Medicine and Surgery in March and April of 2008, the 24 percent figure of new dyspareunia for PROLIFT®

Page 269

patients is based on the responses to the questionnaires.
That's a true statement, correct?
A. It might be. But we are not -- we didn't evaluate -- that's not what we used to characterize the de novo dyspareunia -- de novo dyspareunia rate.
We assessed de novo dyspareunia with the questionnaires by asking, do you have pain with intercourse now and did you have pain with intercourse before surgery? That data is not what we used to calculate the de novo dyspareunia rate for the cohort.
MR. SLATER: Move to strike after "it might be."
BY MR. SLATER:
Q. When you published your article, you decided not to base your figure on the questionnaires, correct? That's a true statement, correct?
A. The de novo dyspareunia rate?

Page 270

Q. Right.
A. We never -- no, that's not correct. We had always planned to assess de novo dyspareunia in the most objective way, which is to evaluate what patients reported at the beginning, when they first came into our practice, on the patient self-administered questionnaires that they receive as a new patient in our practice, where they are asked, are you currently sexually active and are you experiencing dyspareunia.
That is the most objective assessment, because it allows the patient to describe their condition at that time.
We then went back to the charts to look at their six-month follow-ups, where they are also given those questionnaires, and asked then, are you having pain with intercourse now and do you have -- are you sexually active. Asking the patients at the time what they're experiencing now is more accurate than asking them to recollect what they

Page 271

remember.
The only reason we asked them that question in the questionnaire was to be able to correlate the other data in the questionnaire to whether or not the patients were self-reporting de novo dyspareunia.
MR. ISMAIL: Doctor, if the answer to the question is no and he doesn't want an explanation you don't have to give it. So if he asks, is this correct and if you disagree, you can say no. And if he wants an explanation, he'll ask for it.
MR. SLATER: I move to strike that response.
BY MR. SLATER:
Q. Doctor, what I'd like to do it go to Page 173 of your deposition, please.
A. Okay.
Q. And what we're going to do is walk through -- do you remember at the

Page 272

deposition, I walked through your article and I walked through the calculation of de novo dyspareunia based on the questionnaires? Do you remember we did that on Page 173, 174 and 175?
A. Yes.
Q. I'm going to walk through it with you, starting on Line 8 of Page 173. I point out we're on Page E2, because that's where it starts: In the bottom right-hand corner -- paragraph where it says, 56 of the sexually active patients agreed to answer questionnaires, the response rate was 73 percent, meaning 41 responded.
Your answer was: Uh-huh.
And the question: So we know we have a set of 41 that responded, correct?
A. Right.
Q. Now, you were then asked, on Line 18: Then it says, 20 of the 41 sexually active patients who responded to the questionnaires described themselves

Page 273

as pain free?
A. Right.
Q. So 20 out of 41 had no dyspareunia?
A. Right.
Q. And that leaves 21 at the bottom of the page right there who reported dyspareunia?
A. Right.
Q. And you confirmed that and said that was correct, right?
A. Right.
MR. ISMAIL: Improper use of a deposition.
Please wait.
BY MR. SLATER:
Q. The next question, now we're on Page 174.
Question: So 21 out of 41 reported dyspareunia on the questionnaires, correct?
MR. ISMAIL: Same.
BY MR. SLATER:
Q. And what was your answer?

Page 274

MR. ISMAIL: Same objection.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. Then I asked you: If you want to then eliminate the women who had dyspareunia at baseline because you're -- rephrase. If you're trying to eliminate the women who had dyspareunia at baseline because you're trying to study de novo dyspareunia, you would subtract those eight women from both the numerator and the denominator, right?
And what was your answer?
A. That's incorrect.
Q. I'm sorry, what did you say under oath on November 13th, on Line 13?
A. Where is it again?
Q. Page 174, Line 13.
What was your answer to that question?
A. That's correct.
Q. Then --
A. But that's incorrect.

Page 275

Q. Then the next question.
Right. So it would be on the numerator 21 minus eight would be 13 and 41 minus 8 would be 33, correct?
You answered. You said: 18 and 33?
And I answered, I questioned you: 13 and 33. 21 minus 8 equals 13 and 41 minus 8 equals 33, correct?
Your answer, what did you say?
MR. ISMAIL: Objection. Improper use of a deposition.
THE WITNESS: I said: I think that's correct. Math is not my strong point.
BY MR. SLATER:
Q. It's not mine either, but we'll do the best we can.
A. Okay.
Q. Then Page 175, Line 13. Question: 13 -- rephrase. 33 -- rephrase.
13 divided by 33 -- let me start over.
Then on Page 175, Line 13, I asked you: 13 divided by 33? 13 divided by 33 is 39.4 percent. Will you agree to that percentage?
And what was your answer?
MR. ISMAIL: Objection. Same objection.
THE WITNESS: My answer was yes.
BY MR. SLATER:
Q. Okay. Let's move on.
A. For the record, that's incorrect.
MR. SLATER: Move to strike.
BY MR. SLATER:
Q. Now, I want to talk a little bit about something that you wrote in a document to Ethicon. Let's mark this as Exhibit-8.

- - -

(Whereupon, Exhibit Lowman-8, January 2005 E-mails, was marked for identification.)

Page 277

- - -
BY MR. SLATER:
Q. Actually, we'll come back to this.
MR. SLATER: Let's take a five-minute break.
VIDEO TECHNICIAN: Going off the record at 6:14 p.m.

- - -

(Whereupon, a brief recess was taken.)

- - -

VIDEO TECHNICIAN: Back on the record at 6:21 p.m.
BY MR. SLATER:
Q. Doctor, I want to hand you an article that was previously marked in this case as PLT 1095. And I didn't see this article listed on the reliance list in your report.
It was not listed, right?
A. I don't remember. There's several Withagen studies on the reliance list.

Page 278

Q. What I want to do -- sorry?
Start over.
MR. SLATER: Were you able to hear?
VIDEO TECHNICIAN: Yes.
BY MR. SLATER:
Q. We'll start over with this document.
Doctor, I've given you what we marked as PLT 1095. This is an article by several people, including Mariella Withagen, who is an Ethicon consultant that studied the PROLIFT®.
You know that, right?
A. Yes.
Q. And she's evaluating here a comparison of outcomes for various women with mesh surgery, including PROLIFTs®, correct?
A. It looks like that, yes.
Q. And what I want to do is turn to a couple specific things in here. One of them is on Page 1402. 1-4-0-2, the numbers are in the top left.

Page 279

A. Sorry. Top left.
Q. Doctor, in the interest of time, I'm going to ask you a new question.
Doctor, please look at the conclusion at the end of the article.
A. Okay.
Q. And, let me just -- in case you're not aware, this article was identified by Dr. Elliott, one of the experts who testified, as authoritative and medically reliable.
Are you aware of that?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: I don't remember what he testified was authoritative or reliable.
BY MR. SLATER:
Q. I'm going to start over.
Doctor, I want to ask you a question, and I want to make a statement and see if you agree with it, okay?
A. Okay.

Page 280

Q. The increasing number of inserted meshes for pelvic organ prolapse raises concerns. Mesh is successfully used for repair of prolapse, but when complications arise they may be severe in nature and result in a decrease in quality of life. New meshes are introduced into clinical practice despite the lack of proper studies showing their safety and effectiveness. Moreover, the use of easy-to-do mesh kits lowers the threshold for inexperienced surgeons to start operating with meshes. This can only lead to more complications which is harmful for the patients.
Do you agree with that statement?
MR. ISMAIL: Objection.
THE WITNESS: No.
BY MR. SLATER:
Q. Doctor, I'd like to bring your attention now to PLT 1095, which I believe you have in front of you.
A. This one?

Page 281

Q. Yes.
A. Okay.
Q. And this is an article that Dr. Elliott, who testified as an expert in this case, identified as being an authoritative article in the medical literature.
I'd like to represent that to you, okay?
A. Okay.
Q. And if you look at the last page where the conclusion is?
A. Okay.
Q. The very bottom paragraph at the bottom of the conclusion in the left column, do you see, The increasing number? Do you see that phrase?
And if you read that over to the next page, do you see the statement that I just read to you?
A. I do.
Q. And do you disagree with at that statement found in this article?
A. Yes, I do.

Page 282

Q. And this is an article written by Mariella Withagen and other doctors with regard to the PROLIFT® and other products, correct?
A. That's correct.
Q. And you know Mariella Withagen is an investigator who has studied the PROLIFT® extensively, correct?
A. That's correct.
Q. In fact, she is one of the authors of one of those randomized control trials you relied on earlier, correct?
A. That's correct.
Q. And you know that trial, because in that trial she found a 17 percent exposure rate with PROLIFT®, correct?
A. That's correct.
Q. And in the end of that article, she actually concluded that the PROLIFT® should only be used for, in most cases, recurrent prolapse where someone

Page 283

already had a surgical procedure and it happened again? She said that, too, at the end, correct?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: I don't remember what she concluded.
BY MR. SLATER:
Q. Doctor, I'm going to hand you now Exhibit-750.
This is a document produced by Ethicon regarding a meeting regarding a potential PROLIFT® randomized control trial, February 2nd, 2006.
Do you see that?
A. I see that.
Q. And you see the people who attended included Dr. Lucente?
A. Uh-huh.
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And if we go to the next

Page 284

page -- now, certainly, this is not an article -- this is not a document you've ever seen, right?
A. No.
Q. Because you made it clear you didn't rely on any Ethicon internal documents, right?
A. That's correct.
Q. On Page 2 of this document, there's a heading, Recent Problem With PROLIFT®.
Do you see that?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And it says, VL -- that would be Vince Lucente, right?
A. I'm assuming so.
MR. ISMAIL: Objection. Lack of foundation.
BY MR. SLATER:
Q. -- recently removed the center of an anterior PROLIFT® from a

Page 285

Tennessee woman. The device appeared to have been placed too tightly. Patient was in constant pain and had been since two weeks post surgery. Returning for surgery to deal with a bad PROLIFT® will be a disaster.
Do you see that?
MR. ISMAIL: Objection. Lack of foundation. Hearsay.
THE WITNESS: I see that.
BY MR. SLATER:
Q. Were you aware, when you drew your opinions in this case, that Vince Lucente told Ethicon that where you have a patient suffering pain from a PROLIFT® and you have to deal with that PROLIFT®, that the removal surgery will be a disaster?
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. Were you aware of that?
MR. ISMAIL: Objection. Lack of foundation. Hearsay.
THE WITNESS: I was not

Page 286

aware of that.
But removing or undoing any procedure, whether or not there's mesh there or not, is a difficult thing to do.
MR. SLATER: Move to strike from "but" forward.
BY MR. SLATER:
Q. I don't want to generalize.
A. That's not a generalization, that's a qualification.
Q. I wasn't even asking you a question. I was just saying, I don't want to generalize. I'm trying to just ask you about this document and the language in this document, okay, Doctor?
A. Okay.
Q. This document says that, Returning for surgery to deal with a bad PROLIFT® will be a disaster.
That's what Vince Lucente told Ethicon according to this document? Do you see that?
MR. ISMAIL: Objection.

Page 287

Lack of foundation. Hearsay.
THE WITNESS: Yes, I see that.
BY MR. SLATER:
Q. Does that have any impact on any of your opinions in this case?
A. No.
Q. Doctor, I've handed you an Ethicon document entitled Exhibit P-28. That's an e-mail of February 19, 2009.
Do you see that?
A. Yes.
Q. And it's written from Fah Che Leong to Scott Jones.
Do you see that?
A. Yes.
Q. And if you look in the bottom part of the e-mail, you can see that Scott Jones had written to Dr. Leong and asked him about setting up a professional education event about the PROLIFT® at St. Louis University.
MR. ISMAIL: Objection.
BY MR. SLATER:

Page 288

Q. Do you see that?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: Can you ask the question again?
BY MR. SLATER:
Q. Sure.
In this e-mail, you'll see in the middle of the page, Scott Jones wrote to Fah Che Leong regarding setting up a professional education event at St. Louis University to train doctors on the PROLIFT®.
Do you see that?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: Yes, I see that.
BY MR. SLATER:
Q. And Dr. Leong writes back to Scott Jones, and let's read together at the top.
He writes back to Scott Jones and says, I am currently involved

Page 289

in getting a patient to the operating room who had an anterior and posterior PROLIFT® implanted by another physician. She will likely lose any coital function, as her vaginal length is now 3 centimeters and there is mesh extruding literally everywhere. Also, there is a large stone in the bladder from a bladder perforation with the anterior arm.
And then he goes on to say, This patient will have a permanently destroyed vagina, and I am only hoping to get her out of this without more morbidity.
My question is this: First of all, do you agree -- or did you know that women can suffer complications this severe from PROLIFT®?
A. Yes.
Q. And you agree with that, right? That women can suffer complications as severe as stated here, correct?
A. That's correct.

Page 290

Q. That doesn't impact on your opinions at all, seeing this document, right?
A. No. Isolated case reports, as I identified on -- when you're evaluating levels of evidence, are less reliable in formulating overall opinions about how whatever it is that you're evaluating performs in the population.
Q. Do you know whether Ethicon, the doctors who work in medical affairs, whose business it is to evaluate these types of reports, whether they think these types of reports are valuable?
MR. ISMAIL: Objection.
THE WITNESS: I don't know that.
BY MR. SLATER:
Q. Doctor, I've handed you what we marked as Exhibit P-596, and it's a set of e-mails within the company.
And the one at the top is from David Robinson, who I will tell you is a medical affairs director, he was at

Page 291

Ethicon.
And this is in July of 2006, okay?
A. Okay.
Q. And the subject is, Australian PROLIFT® registry.
And if you look at the e-mail, he writes to Jonathan Meek, who is in marketing, and is responding to an inquiry about a registry.
Do you see, it says, You asked about legal risk. I don't know about legal risk, but we clearly have a worldwide customer quality risk. When any adverse event is captured in a registry, it has to be reported to worldwide customer quality. Consequently, if none of our competitors are keeping registries, our complication data may appear increasingly accurate but with decreasing appeal.
Do you see that?
MR. ISMAIL: Objection.
Lack of foundation.

Page 292

THE WITNESS: I see that.
BY MR. SLATER:
Q. Did you know that in Ethicon the medical affairs department and, certainly David Robinson, in this e-mail, decided they don't want to do a registry -- and you know what a registry is, right?
A. I do.
Q. That's where you try to track all patients that get the product, right?
A. Right.
Q. And he says, If we do that, our complication data may be increasingly accurate, but it's going to look worse against our competitors because they're not tracking all the cases --
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. -- that's what he's talking about there?
Do you see that?
MR. ISMAIL: Objection.

Page 293

Lack of foundation.
THE WITNESS: I see that.
BY MR. SLATER:
Q. Is that a good thing for a company like Ethicon, to not want to have a registry to track complications accurately because they're afraid it's going to look bad compared to their competitors?
MR. ISMAIL: Objection.
Lack of foundation. Beyond the scope.
THE WITNESS: I can't speak to everything that they had to consider in making that decision.
BY MR. SLATER:
Q. Let's go to the next document, P-2576.
This is an e-mail dated October 14th, 2011, within the company. Copied to multiple people, including Paul Parisi and some others.
You don't know who Paul Parisi and these other people are, right?

Page 294

A. No.
Q. Well, what I'd like to do show you this, there's a PowerPoint attached, Pelvic Organ Prolapse Condition Business Team Meeting, October 14, 2011.
Do you see that?
A. I see that.
Q. And now what I'd like to do is turn to the page that is numbered 39.
A. Okay.
Q. And do you see at the top it says, There are different patient needs that must be considered before a surgical procedure is recommended?
Do you see that?
MR. ISMAIL: Lack of foundation.
THE WITNESS: Yes, I do.
BY MR. SLATER:
Q. And if you go around, you'll see that there's different types of patients in these black circles.
And the one in the top left says, Young patient, aged 30 to 55?

Page 295

Do you see that?
A. Yes, I do.
MR. ISMAIL: Lack of foundation.
BY MR. SLATER:
Q. And it says, Considerations, maintain sexual function.
So that's a consideration for a young women aged 30 to 55, right?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And if a woman is sexually active and she's within the age range of 30 to 55, an important consideration is maintaining sexual function, correct?
MR. ISMAIL: Same objection.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. It says here in this Ethicon document that for a woman like that, the treatment, sacrocolpopexy or traditional

Page 296

repair? That's what it says in this Ethicon document, correct?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. That is not something you knew that Ethicon internally had a document which said that? You didn't know that before right now, right?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: I did not.
BY MR. SLATER:
Q. Am I correct that has no impact on any opinion in this case, regardless of whether Ethicon thought it or not?
A. On my opinions, no.
Q. Okay. Now, I'll give you Exhibit -- what we've marked as 8.
This is a series of e-mails within Ethicon in January of 2005, about -- under two months before the

Page 297

PROLIFT® went on the market.
You never have seen this, right?
A. No.
Q. At the bottom of the first page, there's an e-mail from Gene Kammerer to Paul Parisi and some other people.
Do you see that? January 18, 2005?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: Gene Kammerer to Kelly Brown, is that what you said?
BY MR. SLATER:
Q. Exactly. Exactly.
A. Okay.
Q. Do you know who Gene Kammerer is?
A. I don't.
Q. Gene Kammerer writes to this group of people and says he had spoken with a professor named Mauro Cervigni, an

Page 298

Italian gynecologist.
Do you see that?
MR. ISMAIL: Objection.
Lack of foundation. Hearsay.
THE WITNESS: Yes.
BY MR. SLATER:
Q. And he then says that there were some important points made by Dr. Cervigni, and he lists them and numbers them.
And I want to focus on the second box, or Number 2. All right? Are you with me?
MR. ISMAIL: Objection.
Lack of foundation. Hearsay.
THE WITNESS: I'm with you.
BY MR. SLATER:
Q. All right. Thanks. It says, Faster tissue repair would prevent complications of erosion and dyspareunia, the latter generally caused by scar contraction. Contraction pulls against the side wall and causes pain. It causes a hard issue, which can be felt by

Page 299

patient and sexual partner. It can lead to a balling up of the mesh which is very uncomfortable.
Are you reading along with me, Doctor?
MR. ISMAIL: Same objections.
THE WITNESS: I'm reading along.
BY MR. SLATER:
Q. First of all, do you agree that when there's mesh contraction, the mesh can ball up and can be very uncomfortable for the woman who has that inside her body?
A. No.
Q. If you look to the continuation of this e-mail, on the next page, Gene Kammerer actually suggests, in the last section, on Number 5, the very top of the page, He confirmed our thoughts regarding the correlation between inflammation, foreign body response and scar formation.

Page 300

I want to stop there.
Do you have any idea what Ethicon's thoughts were on that subject?
A. On inflammation, foreign body response and scar formation? No.
Q. Further down, Gene Kammerer says that -- he's suggesting, As an interim step to reduce erosion and contraction, I am suggesting we market this mesh -- and he named it as ULTRAPRO® Mesh, just above there, for pelvic floor repair.
Do you see that?
MR. ISMAIL: Objection.
Lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Did you know that within Ethicon, just before the PROLIFT® went on the market, that they were discussing the possibility of marketing a different mesh that would reduce erosion and contraction?
MR. ISMAIL: Objection.

Page 301

Lack of foundation.
BY MR. SLATER:
Q. Did you know Ethicon was talking about that?
A. I didn't.
Q. Is that of any significance to you?
A. No.
Q. If you go to the top of the exhibit on the front page, Kelly Brown responds to that e-mail and says, at the bottom of that, I am always pleased to learn of the commonalities in surgeons' observations. Many of the points that Professor Cervigni mentioned have been voiced by other surgeons, which gives me a degree of confidence in considering these issues in our innovative efforts.
Does that have any impact on your opinion that Ethicon internally was getting this information from multiple surgeons?
MR. ISMAIL: Objection.
Lack of foundation.

Page 302

BY MR. SLATER:
Q. About the contraction and the foreign body response?
A. No.
Q. Doctor, I want to ask you a question about whether or not you agree with a statement. And assume the statement is being made in about 2005 -- in 2005, okay?
A. Okay.
Q. We can only advise that caution be exercised when carrying out this new surgical procedure -- and I'm talking about the PROLIFT® procedure.
A. Okay.
Q. -- in fact, experimental studies and clinical trials seem necessary in order to reduce the level of exposure to less than 5 percent of cases.
Do you agree with that statement?
A. In order to expose -- repeat that again.
Q. In order to reduce the level

Page 303

of exposure to less than 5 percent of cases.
Do you agree that the PROLIFT® should have been, on an experimental basis -- only used on an experimental basis in clinical trials until the overall exposure rate could be brought under 5 percent?
MR. ISMAIL: Objection. Mischaracterizes the document that you're reading from.
THE WITNESS: The exposure rate to the PROLIFT® procedure?
BY MR. SLATER:
Q. Right.
A. No.
Q. Doctor, I want to hand you what we marked as PLT 108.
Doctor, PLT 108 is an article written by several authors, including Dr. Cosson.
Do you see that?
A. Yes.
Q. It's dated in 2005, titled,

Page 304

Transvaginal Mesh Technique for Pelvic Organ Prolapse, Mesh Exposure Management and Risk Factors.
Do you see that?
A. I see that.
Q. And you know who Dr. Cosson is? He's one of the inventors of the PROLIFT® and the TVM procedures, correct?
A. Correct.
Q. I'll represent to you this article was found to be were authoritative and medically reliable by Dr. Elliott, our expert, and he testified to that during our case, okay?
A. Okay.
Q. And if you look at the last page, in the conclusion, the last paragraph, it says, We can only advise that caution be exercised when carrying out this new surgical procedure. In fact, experimental studies and clinical trials seem necessary in order to reduce the level of exposure to less than 5 percent of cases.

Page 305

Having seen that now and knowing it's Dr. Cosson that says it, do you agree with that statement?
A. I lost you. I'm on the last page, under -- in the section where it says conclusion. Are you in the first or second paragraph?
Q. The second paragraph. The beginning. You can read it.
A. Okay.
Oh, they're not talking about exposure to the PROLIFT®. They're talking about mesh erosion.
Q. He's talking -- if you want to look at the article, he's not talking about the TVM procedure that became the PROLIFT®?
A. It doesn't seem like it. Because he says in the next sentence, With this particular study, we show that this level is below 1 percent when the uterus is preserved.
MR. SLATER: Move to strike.
BY MR. SLATER:

Page 306

Q. Doctor, if you want to look through the article, you can see that they're talking about the TVM procedure.
A. So in the abstract it says, Prosthetic reinforcement in the surgical repair of pelvic prolapse by the vaginal approach is not devoid of tolerability related problems such as vaginal erosion. The purposes of our study are to define the risk factors for exposure of the mesh material, to describe advances and to recommend a therapeutic strategy.
So they're talking about mesh erosion, not exposure to the PROLIFT® procedure.
Q. If you look through this, you'll see they actually have diagrams that show the TVM technique. For example, on the third page of the article, it shows what a total PROLIFT® looks like.
Do you see that?
A. Yes.
Q. This article is about the

Page 307

TVM technique, isn't it?
A. Yes.
Q. Just very simply, do you agree or disagree with Dr. Cosson that as of 2005, the procedure should have been deemed experimental?
MR. ISMAIL: Completely mischaracterizes the document.
THE WITNESS: No.
BY MR. SLATER:
Q. One last question.
Do you know that article that I just gave you, Doctor? Are you familiar with that article?
A. I've read this article before.
Q. Doctor, as of 2006, with regard to complications of erosion and dyspareunia and the use of PROLENE® soft mesh, which is the mesh in the TVM procedure and the PROLIFT®, would you agree with the following statement: Proposed to improve these phenomenon -- meaning erosion and dyspareunia -- soft

Page 308

PROLENE® recently used by several authors does not appear to fulfill expectations.
Do you agree with that statement?
A. No. I don't even know what the expectations were.
Q. Would you agree that as of 2006, Dr. Cosson and others in his group still had reservations about the widespread use of synthetic meshes?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: No.
BY MR. SLATER:
Q. Doctor, I've handed you what we marked as PLT 0139. And I'll represent to you this is an article that Dr. Elliott testified earlier in the case is an authoritative article, okay?
A. Okay.
Q. Have you seen this article before?
A. It's in French, so probably not.

Page 309

Q. If you turn to the second page, you'll see there's an abstract and a summary in English.
A. Okay.
Q. You've never seen this?
No? You're just shaking your head. I'm sorry. You have to --
A. I'm sorry. Say that again.
Q. I'll start over.
Doctor, have you seen this article before?
A. I may have seen it. I've looked at over 200 articles.
Q. You didn't mention it in your report, did you?
A. No.
Q. Have you seen Dr. Elliott's testimony, by the way, that was given to the jury in this case?
A. I have not.
Q. If you would look in the summary, about halfway down, and you can read down with me, you'll see them talking about erosion and dyspareunia.

Page 310

A. Okay. When you say "halfway down," the first paragraph? Second paragraph?
Q. Halfway down the summary, right in the middle. As you go down to the middle, you'll see them talking about erosion and dyspareunia and the rates of those complications.
Do you see that?
A. Yes, I see that.
Q. And do you see the sentence, Proposed to improve these phenomenon, soft PROLENE® recently used by several authors does not appear to fulfill expectations.
Do you see where I just read?
A. Yes, I see that.
Q. Now, seeing that that was written by Dr. Cosson, do you agree or disagree with that statement?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: Again, I don't

Page 311

know what he means by "does not appear to fulfill expectations."
BY MR. SLATER:
Q. Further down, just about five lines from the bottom of the summary, he says, We still have reservations about widespread use of synthetic meshes.
Seeing that in an article authored by Dr. Cosson and others, that he said that, is that something that you agree or disagree with?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: I disagree with that.
BY MR. SLATER:
Q. Would you agree with me that Dr. Cosson probably has more extensive experience with the mesh -- the soft PROLENE® mesh that ended up in the PROLIFT® and what they're talking about there than you would have had in your practice?

Page 312

A. He probably has more knowledge about GYNEMESH®® than I do, yes.
MR. SLATER: Let's go off the video for a second.
VIDEO TECHNICIAN: Going off the record at 6:48 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 6:50 p.m.
BY MR. SLATER:
Q. Doctor, you offered some opinions earlier about some of the documents Ethicon used to provide information to doctors.
Do you remember that?
A. Yes.
Q. With regard to the monograph, remember you were asked some questions about that?
A. Yes.

Page 313

Q. Do you have any information that shows that Dr. Baker saw the monograph?
A. No.
Q. How about the different patient brochures and IFUs, you're not sure which he may have seen or which he didn't, right?
A. That's right.
Q. Now, let's talk about some of the standards that applied within Ethicon to ensure that warnings in their documents were adequate.
Do you know what any of those standards are?
A. No.
Q. Do you know what any of the medical directors or others in the company said they were supposed to communicate in a warning?
A. No.
Q. Do you know any of the standards that apply in general to medical devices, in terms of what

Page 314

information should be included in something like an IFU or a brochure?
A. No.
Q. Were you curious at all as to what standards Ethicon thought it was required to meet? What its duty was in deciding whether warnings and information were adequate?
MR. ISMAIL: Objection.
THE WITNESS: No.
BY MR. SLATER:
Q. That would have been of no significance to you in forming the opinions you offered here today?
A. No. What they think? No.
Q. In essence, tell me if I'm right, your warning opinions are based on your own evaluation of what information you would need in your own medical practice; is that correct?
A. Me and my colleagues, not just me, but physicians in general.
Q. Let's look at your deposition, Page 134; Page 134, Line 13.

Page 315

I asked you: If I understand correctly, with regard to the warning opinions, those are based on your own evaluation of what information you would need in your practice; is that a correct statement?
What answer did you give under oath last month?
A. That's correct.
Q. So, again, your warning opinions go to what you would personally need in your own practice, correct?
A. Not just my practice, but the practice of my colleagues as well.
Q. Please look at Page 133, Line 22.
The question you were asked: In offering your opinions with regard to whether the information provided in the patient brochure was adequate, were you basing that upon your own evaluation of what information you would personally need in your practice?
And what answer did you

Page 316

give?
A. Yes.
Q. Coming back to the monograph, which you were asked questions about, do you even know whether the monograph, which is dated, on the copy you used, 2007, whether that was even available when Dr. Baker was trained?
A. I don't.
Q. Do you know that Dr. Baker was trained before 2007?
A. I do.
Q. And, again, you have no information indicating Dr. Baker ever saw that document, right?
MR. ISMAIL: Asked and answered.
THE WITNESS: That's correct.
BY MR. SLATER:
Q. Do you have any information as to which patient brochure Dr. Baker said he saw?
MR. ISMAIL: Asked and

Page 317

answered.
THE WITNESS: I don't.
BY MR. SLATER:
Q. You don't know what professional education information Dr. Baker would have seen, correct?
A. I don't.
Q. Would you at least agree with me, regarding warnings, that Ethicon needed to accurately warn about the risks they knew?
A. No.
Q. They didn't need to accurately warn about the risks they knew existed with the PROLIFT®?
A. When you're talking about warning, there's a lot that goes into deciding what to disclose and what not to disclose. So my answer to that is no.
Q. If Ethicon knew something to be true -- withdrawn.
You testified, regarding the warnings, that doctors know certain risks and understand certain things and that

Page 318

you think the warnings are adequate.
You said that, right?
A. Yes.
Q. Did you see Dr. Baker's testimony?
A. I did.
Q. Do you know the testimony that was presented to the jury --
A. When you're saying "testimony," you're talking about deposition?
Q. Right. That was played to the jury in this case?
A. I've read his deposition.
Q. Did you see that Dr. Baker said he didn't know all the risks and didn't understand them, and when he learned them he stopped using the PROLIFT®?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: That wasn't what I got from his deposition.
BY MR. SLATER:

Page 319

Q. Did you see where he said that when he learned more about the pain and the erosions and things like that, he stopped using the PROLIFT®?
MR. ISMAIL: Objection.
THE WITNESS: I don't remember that.
BY MR. SLATER:
Q. Did you see that Dr. Baker said he stopped using the PROLIFT®?
A. I do remember that, yes.
Q. Did you see that he said he stopped using the PROLIFT® when he learned about the complications, learned more than he knew initially?
MR. ISMAIL: Objection.
THE WITNESS: I don't remember that.
BY MR. SLATER:
Q. Did you see in Dr. Baker's testimony that he said he stopped using the PROLIFT® because he determined, based on the experience he was gathering, that it was unsafe for his patients?

Page 320

MR. ISMAIL: Objection.
THE WITNESS: I don't remember that.
BY MR. SLATER:
Q. Do you know, as you sit here now, why Dr. Baker stopped using the PROLIFT®?
A. I don't.
Q. One of the things that you told me previously is that you're familiar with the literature of Dr. Klinge? Remember you told me that when we met?
A. Yes.
Q. And Dr. Klinge, are you aware, testified in this trial by video?
A. I am, yes.
Q. Have you seen that testimony?
A. I have.
Q. When did you see that?
A. Oh, I don't remember. At some point in reviewing these materials, I have seen his -- his testimony in this

Page 321

trial you're saying?
Q. Right.
A. I think I did see that, yes.
Q. His literature is certainly important to you, right?
A. Yes.
Q. And in forming your opinions, you relied, in part, on his literature, correct?
A. That's correct.
Q. Do you know whether Dr. Klinge offered the opinion as to whether or not the PROLIFT® is safe or not?
A. From what I remember from his deposition, I think he did.
Q. Do you remember what he said in his deposition?
A. He said that he felt like -- I don't remember if he said it was unsafe. I do remember him saying that he thought that VIPRO® would be better option.
- - -
(Whereupon, Exhibit

Page 322

Lowman-9, Excerpt of Testimony of Dr. Klinge, was marked for identification.)

- - -

MR. SLATER: I'm marking this as Exhibit-9.

BY MR. SLATER:

Q. Doctor, I've handed you the testimony that we submitted at trial.

And if you can turn to Page 23, this is Dr. Klinge's testimony.

A. Okay.

Q. And Dr. Klinge, in clip 38, it starts at Page 78, Line 6, was asked: After your review of all the materials in this case regarding Ethicon's meshes for treating pelvic organ prolapse, all of your work that you've done in the scientific literature, conferences you've spoken at around the world, the conferences you've spoken as an invited lecturer by Ethicon, and your work as a hernia surgeon, both implanting and explanting polypropylene meshes, your

Page 323

work in reviewing thousands of hernia mesh explants from humans, your review of looking at explants from the pelvic floor -- from the pelvic floor of women, do you have an opinion, to a reasonable degree of medical and scientific certainty, as to whether the PROLIFT® was a safe design or an unsafe defective design?

And you see he then says he has such an opinion.

And then his opinion is asked for on Page 79, Line 11, and he answers: The PROLIFT® carries unnecessary risk and, therefore, it's unsafe.

Had you -- you had read this, is that your testimony?

MR. ISMAIL: Objection.

BY MR. SLATER:

Q. You had seen this before today?

A. No, I didn't. It must have been his report.

Page 324

Q. Dr. Klinge's opinion that the PROLIFT® is unsafe, that is significant to you, based on his work in this field, correct?

A. No.

Q. Look at Page 43 of your deposition, please. Actually, start at Line 2.

I asked you at your deposition: So you're not aware of whether Dr. Klinge has offered an opinion directly about whether or not the mesh in the PROLIFT® is safer for use to treat prolapse through the PROLIFT® system?

Your answer was: That's correct.

Because at that time you weren't aware of his opinion, correct?

A. That's correct.

Q. And then I asked you: Based on Dr. Klinge's work in this field, would that opinion be significant to you?

And what did you say?

A. It would be something that I

Page 325

would consider, yes.

Q. Is it still something that you would consider, now that I've showed you that he has testified to this jury that the PROLIFT® is unsafe?

A. I -- his work in this field has been significant. What's been published in the literature, I've reviewed and considered that.

His opinion about whether or not the PROLIFT® is safe is something that I would consider. It's not something that I would consider in lieu of the multiple randomized control trials, the Cochrane review and all of the hundreds of studies that have been published about the PROLIFT® and its safety and efficacy.

Q. Dr. Klinge's opinion certainly is an important piece of information, right?

A. Dr. Klinge's work is important. His opinion in the trial is less important.

Page 326

Q. Are you aware that the opinion he's offered in this trial is consistent with his medical literature?
A. No.
Q. Do you know that he testified that he published an article where he tested the PROLIFT® mesh and found that the pores collapse and that's unsafe for people?
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. And that he testified to that at trial?
A. I'm not aware of that.
Q. Let's talk about Patricia Hammons now.
A. Okay.
Q. One thing you wanted to do was approach the evaluation of Patricia Hammons like the evaluation of any patient, right?
A. Right.
Q. And you would want to evaluate her condition just like you

Page 327

would in your medical practice, right?
A. Right.
Q. And in your medical practice, you examine your patients, right?
A. Right.
Q. That's because an examination is very critical to you forming a solid opinion about what's happening with the patient, right?
A. Yes. It gives you greater information.
Q. In fact, you would not, for example, recommend a course of treatment to one of your patients without examining the patient; you'd want to examine her, right?
A. That's correct.
Q. Here, you did not examine Patricia Hammons, correct?
A. That's correct.
Q. And not having your own examination of Patricia Hammons is a piece of important information you just

Page 328

don't have because you haven't examined her, correct?
A. That's correct.
Q. Did you speak to any of Patricia Hammons' treating doctors?
A. No.
Q. Did you try to at any point?
A. No.
Q. Let's talk about a few things first.
The stage of prolapse that Patricia had when she first was seen by Dr. Baker and went in for the surgery, you said that Dr. Baker called it a grade 4, right?
A. Right.
Q. You don't know what criteria he used, right?
A. I'm assuming he used the Baden and Walker system. That's when we -- when we say the word "grade," that's what that indicates.
Q. That's your assumption, but that's not documented anywhere?

Page 329

A. Well, that is the documentation. When you say grade 4, that means you're using the Baden and Walker system. If you're using the POP-Q system, it's a stage.
Q. Did Dr. Baker document the findings on the exam in such a way that he said, I found this and that's why I'm calling it this grade?
A. No.
Q. And your basis for finding that there was a grade 4 prolapse is just because Dr. Baker called it a grade 4, right?
A. No. That's -- like what I testified to before, it's -- that is part of the what I'm basing that opinion on, but also the fact that she currently has a stage III and is asymptomatic.
Q. Can you look at Page 2073 of your deposition, please?
On Page 207, at Line 12, you were asked: Why do you call it a stage IV prolapse preoperatively? What is it

Page 330

about Dr. Baker's exam that tells you it was a stage IV?
And what was your answer?
A. I'm sorry, can you start over?
Q. Sure.
A. Page 207?
Q. Let's go to Page 207 of your deposition.
A. Okay.
Q. And on Line 12 you were asked: Why do you call it a stage IV prolapse preoperatively? What is it about Dr. Baker's exam that tell you it's a stage IV?
And your answer: Because he called it a stage IV, and I would assume that somebody that operates on patients that have pelvic organ prolapse understand what stage IV prolapse is, regardless of whether or not they can assess POP-Q measurements.
That was your answer under oath, correct?

Page 331

A. That's correct.
Q. If, in fact, she was a stage II, would that have any impact on your opinions?
A. No.
Q. Now, most of the time -- well, let me take a step back.
When Dr. Baker assessed Patricia Hammons, she had no pain, correct, preoperatively?
A. Correct.
Q. Before the PROLIFT®, no pain, right?
A. That's correct.
Q. No dyspareunia, correct?
A. That's correct.
Q. And no incontinence, right?
A. That's correct.
Q. Your procedure of choice for a symptomatic cystocele -- or for a cystocele like what you think Ms. Hammons had is an abdominal sacrocolpopexy, correct?
MR. ISMAIL: Objection to

Page 332

the form of that question.
THE WITNESS: Can you re-ask the question, please?
BY MR. SLATER:
Q. Sure. Let me ask it more directly.
A reasonable treatment option for Patricia Hammons, in May 2009, would have been abdominal sacrocolpopexy, correct?
A. That's correct.
Q. You mentioned smoking before.
In this case, Ms. Hammons healed normally after the surgery, correct?
A. After which surgery?
Q. Dr. Baker's surgery.
A. She did.
Q. Her healing was not impacted in any way by her smoking that you can see, right?
A. That's correct.
Q. Now, a couple of quick

Page 333

questions about a few things you mentioned.
You mentioned IC, interstitial cystitis. Do you remember you mentioned that?
A. Yes.
Q. And that's when somebody has discomfort in their bladder?
A. It's a clinical syndrome that's defined by urgency, frequency and bladder pain.
Q. It's not characterized by vaginal pain on intercourse, is it?
A. Dyspareunia is one of the symptoms of interstitial cystitis.
Q. Did any doctor ever diagnose that?
A. No.
Q. Did any doctor ever put it in a differential of diagnosis of potential causes?
A. No.
Q. Did any doctor ever suggest it might be an issue with Patricia

Page 334

Hammons?
A. No. No one other than me.
Q. You talked about Dr. Lackey and some of his findings about what was causing Patricia Hammons' issues.
Do you remember that?
A. Uh-huh.
Q. Dr. Lackey didn't know Patricia had a PROLIFT®, did he?
A. I believe he testified that he did not know that. I think that's correct.
Q. If he didn't know there was a PROLIFT®, he wouldn't be in a position to make a full evaluation of what was causing her issues, because he doesn't know she has that system in her body, right?
A. I don't think that's true.
Q. So you think Dr. Lackey can form an opinion about what is causing Patricia's issues without knowing that she has the PROLIFT® in there and that that might be a cause also?

Page 335

A. He documented his physical exam findings and what she was complaining about and drew his opinions based on that.
Q. But he didn't know what was going on inside her body because he didn't know she had a PROLIFT®, right?
MR. ISMAIL: Objection.
THE WITNESS: He knew that she had a mesh, because she told him she that had -- that she thought they used mesh.
BY MR. SLATER:
Q. He thought it was a TVT, right?
A. I believe he commented that, yes, in her subsequent evaluations.
Q. That's a small strip of mesh that goes underneath the urethra; much smaller and much less mesh than a PROLIFT®, right?
A. Yes.
Q. With your own patients, you have seen your own patients where they

Page 336

have scarring of the mesh causing banding of the mesh, tense areas of the mesh that are tender or painful when touched, right? You've seen that with your own patients, right?
A. I have.
Q. And Dr. Heit found this to be present with Patricia Hammons, correct?
A. Correct.
- - -
(Whereupon, Exhibit Lowman-10, Chart, was marked for identification.)
- - -
BY MR. SLATER:
Q. Doctor, I've provided you a list and I'd like to go through it with you and ask you to confirm, if you could, that the medical records document the things that we have set forth on this list, okay?
Let me start over. I've marked as -- rephrase.

Page 337

I've marked for identification Exhibit-10, is that correct?
A. Yes.
Q. This document.
And you see in front of you it's a list of dates and information about each date?
A. Yes.
Q. Doctor, what I'd like to see if you can confirm for me is whether the medical records document each of the findings that we've listed on this chart, okay?
A. Okay.
Q. So August 30th, 2012, patient's pain from anterior vaginal mesh.
That is in the medical record, correct?
A. That's correct.
Q. August 30, 2012, tense, tender anterior vaginal wall after vaginal mesh.

Page 338

That's in the medical record, correct?
A. That's correct.
Q. September 13, 2012, dyspareunia secondary to anterior wall mesh.
That's in the medical record, correct?
A. That's correct.
Q. And "secondary" means caused by, correct?
A. That's correct.
Q. November 8, 2012, pain and dyspareunia from anterior vaginal wall mesh, right?
A. That's correct.
Q. Urinary incontinence from low bladder compliance, likely related to mesh as well.
That is what's documented in Dr. Heit's record, correct?
A. That's correct.
Q. Tense, tender anterior vaginal wall after vaginal mesh.

Page 339

Again, documented in Dr. Heit's medical record, correct?
A. Correct.
Q. And just to be clear, you, as a doctor, and you, as an expert, what's most important to you is what's in the medical records, right?
A. In determining my opinions about her clinical course, yes.
Q. November 26th, 2012, mesh erosion, anterior wall.
That's in the record, right?
A. That is.
Q. Tense, tender anterior vaginal wall after vaginal mesh.
Again, that's documented by Dr. Heit, correct?
A. That's correct.
Q. November 28, 2012, pelvic pain and dyspareunia secondary to mesh exposure.
Documented by Dr. Heit, correct?
A. That's correct.

Page 340

Q. Again on November 28, 2012, shards of mesh at base of bladder.
That's documented by Dr. Heit, correct?
A. I believe so. After his excision. I think so.
Q. There were -- there were shards of mesh that he couldn't get out of the bladder that he had to leave inside the bladder, correct?
A. No. That was --
Q. On the bladder wall?
A. There was mesh left in the -- incorporated into the bladder during his repair, yes.
Q. December 13, 2012, good portion of anterior wall mesh was adherent if not eroding through the bladder.
That was documented by Dr. Heit, correct?
A. Yes.
Q. January 4, 2013, good portion of anterior wall mesh was

Page 341

adherent if not eroding through bladder.
He documents that again, correct?
A. That's correct.
Q. January 24, 2013, pain from anterior vaginal wall mesh placement for cystocele.
Documented in the record by Dr. Heit, correct?
A. That's correct.
Q. January 28, 2013, erosion of vaginal mesh into bladder.
Documented by Dr. Heit in the medical record, correct?
A. That's correct.
Q. Doctor, in forming your opinions in this case, you accept Ms. Hammons' reports to her physicians and those who have examined her that she has had pelvic pain and dyspareunia after the PROLIFT® surgery and reporting when she had it and what she felt? You accept that, correct?
A. Correct.

Page 342

MR. SLATER: Let's go off.
VIDEO TECHNICIAN: Going off the record at 7:13 p.m.
- - -
(Whereupon, a brief recess was taken.)
- - -
VIDEO TECHNICIAN: We're back on the record at 7:15 p.m.
MR. SLATER: Doctor, thank you very much. I don't have any other questions on cross-examination.
THE WITNESS: Thank you.
- - -
EXAMINATION
- - -
BY MR. ISMAIL:
Q. Dr. Lowman, it's getting late in the evening. I don't intend to be very long. I appreciate your patience today.
I'd like to begin where Mr. Slater left off. Do you still have in

Page 343

front of you Exhibit-10?
A. I do.
Q. So Dr. -- Mr. Slater began this summary of medical records on August 30, 2012?
A. Yes.
Q. And does it end on January 28, 2013?
A. Yes.
Q. I want to focus on the end.
Have you seen any records after January 28th from 2013, in any way from Mrs. Hammons' treating physicians, documenting problems with -- that mesh is causing her problems?
A. No.
Q. So using Mr. Slater's own chart, is there anything on Mr. Slater's chart after January 28, 2013, that documents that any of Mrs. Hammons' treating physicians believe mesh was causing her any problems?
A. No.
Q. Did you see anything in the

Page 344

testimony of any of her treating physicians, after January 28th, 2013, that any of them considered that mesh was causing her any problems?
A. No.
Q. Going to the findings that are reported here, did you, on direct examination, go over Dr. Heit's findings that are reflected on Exhibit-10?
A. I did.
Q. Did Dr. Heit explain what he concluded, as part of his care and treatment, was the reason why the mesh was bunched and presenting the way it did to him in 2012?
A. He did.
Q. What was Dr. Heit's explanation for why the mesh was in the condition it was in, in 2012?
A. Improper placement.
Q. Do you agree with Dr. Heit's conclusion in that regard?
A. I do.
Q. Did Dr. Heit, anywhere in

Page 345

his records or in his testimony, conclude that the mesh had contracted?
A. No, he didn't.
Q. Did Dr. Heit conclude, anywhere in his records or in his testimony, that there was something wrong with the mesh that resulted in problems for Mrs. Hammons?
MR. SLATER: Just for the record, this line of questioning about the cause of the mesh, that's beyond the scope of the direct. I didn't ask any questions about that. We move to preclude the entire line of the questioning -- that's what I meant, beyond the scope of cross.
MR. ISMAIL: You may answer.
THE WITNESS: No.
BY MR. ISMAIL:
Q. Now, turning to Dr. Lackey, I don't know if you still have it there with you, and I can pull it up on the screen, but it's Exhibit D -- Defense

Page 346

Exhibit 100043.4. And I can put it up on the record.
A. Yeah, I think it will be easier for me to just look there.
Q. So counsel asked you --
MR. SLATER: Just for the record. I object to this. I didn't go through medical records. I object.
MR. ISMAIL: Let me get my question out, please.
BY MR. ISMAIL:
Q. Did Mr. Slater ask you what Dr. Lackey believed was the mesh that Mrs. Hammons had in 2009?
A. He did.
Q. Is that conversation between Ms. Hammons and Dr. Lackey documented in this record?
A. On that -- on this date, it says that, She thinks they used mesh and those symptoms are better.
Q. Let's look at the immediately prior sentence. Her uterus

Page 347

is coming out and bladder was dropped. Correct?
A. Correct.
Q. It says, She thinks they used mesh and those symptoms are better. Is the TVT used to treat a pelvic organ prolapse?
A. It's not.
Q. So in terms of the mesh that was described to Dr. Lackey in November of 2009 for the treatment of pelvic organ prolapse, could that have been the TVT?
A. No.
Q. Now, with respect to the abdominal sacrocolpopexy in 2009, is that surgical treatment indicated for treatment of a bladder prolapse, in 2009?
A. It's indicated for the treatment of apical prolapse.
Q. Did Mrs. Hammons have an apical prolapse?
A. She did.
Q. Did you review Dr. Baker's testimony to see whether he was even

Page 348

equipped to do an abdominal sacrocolpopexy?
A. I did.
Q. And what do you recall was his testimony?
A. He was not.
Q. So to the extent an abdominal sacrocolpopexy would have been appropriate for Mrs. Hammons in 2009, would that have been for the apical prolapse that she had?
MR. SLATER: Objection.
THE WITNESS: It would have been an appropriate -- it would have been an appropriate option for treatment of her apical prolapse. However, it was not an option for her because her treating doctor was not able to perform that procedure.
BY MR. ISMAIL:
Q. Now, I want to turn to the discussion of your study that you had with Mr. Slater, okay?

Page 349

A. Okay.
Q. Do you recall what exhibit number that was?
A. 0302.
Q. Okay. Dr. Lowman, were you one of the authors of this paper?
A. Yes.
Q. Was this paper submitted for peer review?
A. It was.
Q. Was this paper -- explain to the jury what the peer review process is.
A. The peer review process is when we submit abstracts for consideration for presentation, our peers, or colleagues, review the abstracts and assess the quality of the data, the content of the data and decide whether or not they think it's something worth presenting.
Q. How about -- and I'm actually looking at the published article.
A. Okay.

Page 350

Q. So with respect to peer review of an article that ends up in a journal, how does that process work?
A. You submit your article for presentation. They evaluate the article and decide whether or not it's publish worthy.
Q. And what journal was this article published in?
A. The American Journal of Obstetrics and Gynecology.
Q. And what is the significance of that journal to the practitioners in the field?
A. It's one of the lead journals in obstetrics and gynecology.
Q. Did your article and your description of the patients and the methods you employed, was that accepted by this journal for publication?
A. It was.
Q. Did the description of the study and the methods you employed and everything that you went through with Mr.

Page 351

Slater, did that go through peer review?
A. It did.
Q. Now, you were describing for Mr. Slater what the purpose of this study was.
Do you recall that discussion?
A. I do.
Q. And there was a discussion of whether you would use questionnaires or some other method to assess whether patients developed painful intercourse after the PROLIFT®.
Do you recall that?
A. I do.
Q. For the design of this study, what was the study -- the clinical researchers' method for assessing the development of painful intercourse following surgery?
A. The method was to evaluate their charts to assess baseline dyspareunia, because that's the most objective assessment, and evaluate their

Page 352

charts to assess the development of de novo dyspareunia or dyspareunia after the indexed procedure.
If the chart was incomplete on that data, then we called the patients and asked them, do you have painful intercourse? Well, first we asked them, are you sexually active? And then, do you have painful intercourse?
Q. Did -- why did you believe that doing the study in that manner -- withdrawn.
Do you believe that doing the study in that manner resulted in the most reliable data that you could share with the medical community?
MR. SLATER: Objection. Leading.
THE WITNESS: Yes.
BY MR. ISMAIL:
Q. Why?
A. Because you're assessing a rate of the development of an outcome. So in doing that, you have to know

Page 353

whether or not that outcome was present at the baseline, which we did know because patients answered questionnaires, what we called intake questionnaires.
That means when they present to our practice, they answer a questionnaire about what they're presenting with. So any patient that comes in for us -- to us -- or any patient that came in to us for evaluation was given one of those questionnaires to fill out.
On that questionnaire, it says, are you sexually active? And, do you have pain with intercourse? Two separate questions. So it's a objective assessment of what the patient is feeling then. That is the most accurate assessment.
When we then looked at whether or not they developed de novo dyspareunia after surgery, they also fill out that same questionnaire when they come back to see us for a six-month

Page 354

postop check, which is what I explain in the paper.

So we have a preop assessment that's subjective and asks them about what they're feeling then. We have a six-month assessment that also asks them about what they are feeling then.

If we had not had patients -- say we had performed a PROLIFT® on a patient and they were three months postop, then I picked up the phone and called them and asked them, are you sexually active? Do you have painful intercourse? That's why that assessment was done with chart review and telephone assessment.

In the questionnaires, we asked them, do you have painful intercourse? Did you have painful intercourse before surgery? That was not to calculate de novo dyspareunia rate. That was to classify the answers in the questionnaire.

Page 355

Q. So -- go ahead. I didn't mean to cut you off.

A. The questionnaires that were sent out, 41 were answered. Of the 41 that answered the questionnaire, eight reported dyspareunia at baseline, therefore, 13 out of the 41 that answered the questionnaire had de novo dyspareunia.

The denominator is not the number of patients that were sexually active, it's the number of patients that answered the questionnaire.

Q. So in terms of the calculation that Mr. Slater was trying to do on his examination, do you believe that that was an appropriate calculation to undertake based on the design of the study?

A. Yes. That is the most appropriate way to evaluate that, that's why this paper won a research award at the Society of Gynecologic Surgeons.

Q. I think I had a negative

Page 356

somewhere in my question, so let me re-ask it.

First, let me ask it this way: Do you believe that your method of examining de novo dyspareunia in this paper was the appropriate method?

A. Yes.

Q. And why is that?

A. Because of exactly what I just said. You can't -- if you have a questionnaire that's an anonymous questionnaire, there is no way for me to tell whose answer belongs to who, you can't assess a de novo dyspareunia rate that way.

Q. Was your paper recognized as being of distinction in the medical community?

MR. SLATER: Objection.

THE WITNESS: Yes, it was.

BY MR. ISMAIL:

Q. Please tell us about that.

A. So the Society of Gynecologic Surgeons -- every medical

Page 357

conference that we have is a conference about research. So people present their data, present their research. And not everyone is selected to do that.

The papers that are thought to be most impactful are selected for presentation, so that the peers that are at the meeting can evaluate the paper, criticize the paper, analyze the paper and decide whether or not they think it's something that's relevant. So not even every paper is selected for presentation, number one.

But then also certain papers are given awards, if they think that the research is outstanding. And my paper was given one of those awards.

Q. Was the critique that Mr. Slater did of your paper, do you believe that was valid?

A. No.

Q. This information that you've published here, Doctor, was this out in the scientific community as of what date?

Page 358

A. 2008.
Q. I want you to turn to Page E4 of your paper and go to Table 4.
Now, in Table 4, do you compare the rate of dyspareunia that you detected in your study compared to alternative options to treat pelvic organ prolapse?
MR. SLATER: Objection. This is far beyond the scope of what I asked her on cross-examination.
THE WITNESS: I did.
BY MR. ISMAIL:
Q. What was the rate of de novo dyspareunia that you reported?
A. 16.7 percent.
Q. Is that anywhere near the 30-plus percent that Dr. Weber said was in your paper?
A. No.
Q. Looking at Table 4, how does the PROLIFT® compare to these other treatment options that are reflected in

Page 359

this table on this question of de novo dyspareunia?
A. It compares favorably.
Q. Doctor, on this question of -- counsel talked to you about -- withdrawn.
I'm going to hand you what has been marked as Defense Exhibit-31991.
And, Doctor, are you familiar with this paper?
A. I am.
MR. SLATER: I object. This is beyond the scope. The doctor wasn't asked about this article at all.
MR. ISMAIL: It doesn't matter.
MR. SLATER: It doesn't?
MR. ISMAIL: No.
MR. SLATER: How is this implicated by the scope of cross-examination?
MR. ISMAIL: Because you covered risk/benefit.

Page 360

MR. SLATER: Oh, come on.
BY MR. ISMAIL:
Q. Doctor, is this an article by de Landsheere?
A. It is.
Q. Is this one of the papers you considered in this case?
A. It is.
Q. Is this paper authoritative?
A. It is.
Q. Is it reliable?
A. Yes.
Q. Is this -- what type of study is this, that's being reported here?
A. This is a retrospective single-center study including 524 patients who were followed for three years -- a median of three years.
MR. SLATER: I just want to make it clear, I'm objecting. Not only is this beyond the scope, the doctor was not asked about this article. There's a ton of

Page 361

articles on her reliance list.
Are you now going to go through all of them? Of course not. And it's hearsay.
BY MR. ISMAIL:
Q. Doctor, I want to ask you to turn to the last part of the article, if I could.
A. The last page?
Q. Yes. Of the article.
A. Okay.
Q. You indicated this was three-year follow-up data; is that correct?
A. That's correct.
Q. Approximately how long did Mrs. Hammons have her PROLIFT® before Dr. Heit surgically removed it?
A. About three years.
Q. And if you look to the right column, the paragraph that begins, In conclusion.
A. Yes.
Q. I want to direct you to the

Page 362

bottom part of that.
Does this read, The three years median follow-up result showed that this procedure is safe and effective in the median term?
Did I read that correctly?
A. Yes.
Q. And "this procedure," what does it relate to that's being described here?
A. Complications.
Q. What specific surgical procedure? Does this relate to the PROLIFT®? Let me ask it that way.
A. Yes.
Q. So the conclusion of this paper, what does it say about whether the PROLIFT® is a safe and effective treatment for pelvic organ prolapse, at least for the period of time in which Mrs. Hammons had it?
A. It's saying that it's safe and effective.
Q. Do you agree with these

Page 363

results?
A. I do.
Q. Counsel asked you a lot of questions about internal e-mails and policies that may or may not be a part of Ethicon.
Do you recall all that?
A. Yes.
Q. Doctor, are you aware of any scientific methodology that looks to internal e-mails to answer a scientific question?
MR. SLATER: Objection.
THE WITNESS: No.
BY MR. ISMAIL:
Q. Is the use of individual e-mails part of what you do as a clinical researcher to answer scientific questions?
A. No.
Q. Individual case reports, Mr. Slater should showed you a case of a single patient having a complication, or another patient having a complication.

Page 364

Do you recall that?
A. I recall that.
Q. Where do individual case reports like that fall on the levels of reliability that researchers such as yourself use when answering scientific questions?
MR. SLATER: Objection.
Again, beyond the scope.
THE WITNESS: It's the lowest level.
BY MR. ISMAIL:
Q. When you were asked to investigate the issues and to share your findings with the jury, what approach to answering scientific questions did you bring to this case?
A. As I described before, I used evidence-based medicine, which means that you specifically rely on the most reliable science, the most reliable evidence.
The de Landsheere study is more reliable than many of the studies

Page 365

that we talked about, that Mr. Slater talked, about because it's got a larger group of patients. Larger cohort studies are more reliable than smaller cohort studies.
In making my opinions, or in coming to my conclusions, I used the highest levels of evidence.
In medicine, in any scientific field, there are controversies. Some people will think one thing, other people will think something else. The way that those controversies are settled is through the literature, as long as everyone is practicing evidence-based medicine.
If some people choose to ignore the levels of evidence and rely on unreliable or less reliable evidence, then the controversy just persists.
Q. Does -- counsel asked you whether you would be interested in learning about discussions that were happening within Ethicon or e-mails that

Page 366

were exchanged within Ethicon.
Does any of that meet the criteria of reliability that a researcher would use when using evidence-based medicine to answer scientific questions?
A. No, it's not. We don't even have access to that, nor should we.
Q. Is that why, in this case, when you did your investigation as a researcher you didn't look to those documents?
A. That's correct.
Q. Counsel asked you whether abdominal sacrocolpopexy is a go-to procedure, or some words to that effect.
Do you recall that question?
A. I do.
Q. What is the mesh that you used in your abdominal sacrocolpopexy procedure?
A. GYNEMESH®.
Q. What is the mesh that was part of the PROLIFT® kit?
A. GYNEMESH®.

Page 367

Q. Lastly, Dr. Lowman, Mr. Slater asked you questions about Dr. Lucente and whether you respect him, or words to that effect.
Do you recall that?
A. I do.
Q. Has Dr. Lucente, to your knowledge, been recognized in the field of urogynecology?
MR. SLATER: Objection.
THE WITNESS: He has.
BY MR. ISMAIL:
Q. How recently?
A. Just this year's AUGS meeting. He was given an award, I believe it was the Raymond Lee Lectureship Award, which is the equivalent of a lifetime achievement award from the American Urogynecologic Society.
Q. Is that an award of some significance in your mind?
A. Absolutely.
MR. SLATER: Objection.

Page 368

Leading.
MR. ISMAIL: Dr. Lowman, that's all I have for you. Thank you very much.
THE WITNESS: Thank you.
- - -
EXAMINATION
- - -
BY MR. SLATER:
Q. Doctor, I'm just going to follow up with a few questions.
Are you aware that Ethicon is a member of AUGS?
A. No.
Q. Did AUGS see the internal e-mails at Ethicon about Dr. Lucente when they gave him that award?
A. Probably not.
Q. You were just asked a question about your use of GYNEMESH® PS for your abdominal sacrocolpopexies.
Do you remember that question a few minutes ago?
A. Yes.

Page 369

Q. And you're aware, are you not, that GYNEMESH® PS mesh is only indicated by the manufacturer to be put in abdominally? You know that, right?
A. I did not know that.
MR. SLATER: Off the record for a second.
VIDEO TECHNICIAN: Off the record. 7:37 p.m.
- - -
(Whereupon, a discussion off the record was held.)
- - -
VIDEO TECHNICIAN: Back on the record at 7:38 p.m.
- - -
MR. ISMAIL: Object to the form of that question as violating motion in limine.
BY MR. SLATER:
Q. Doctor, you just testified about your use of GYNEMESH®® PS a few minutes ago when defense counsel asked you some questions, correct?

Page 370

A. Yes.
Q. And this is the IFU for GYNEMESH®®® PS.
Do you see that?
A. I see this, yes.
MR. ISMAIL: Objection to the form. Violates motion in limine.
BY MR. SLATER:
Q. And if you look at the indications, it talks about the use of the GYNEMESH®®®, and it indicates -- it's indicated for use as a bridging material for apical vaginal and uterine prolapse. For surgical treatment, laparotomy or laparoscopic approach is warranted.
Do you see that?
A. I see that.
MR. ISMAIL: Objection.
BY MR. SLATER:
Q. You weren't aware that Ethicon had limited the indications of GYNEMESH®®® PS only to be placed abdominally through either a laparotomy

Page 371

or laparoscopic approach?
A. It doesn't --
MR. ISMAIL: Objection. Sorry. Dr. Lowman, before you start your answer.
Objection. Violates motion in limine and stipulation.
THE WITNESS: That's not what it says. It says it's indicated for being a bridging material in apical vaginal and uterine prolapse. It doesn't say it's only indicated in abdominal implantation.
BY MR. SLATER:
Q. Is it your testimony, Doctor, that GYNEMESH®®® PS is indicated by Ethicon to be placed transvaginally through the vagina now?
MR. ISMAIL: Objection. Violates motion in limine and stipulation.
THE WITNESS: I don't know what they have said it's indicated

Page 372

for. I'm interpreting the sentence that you just had me look at, and it doesn't say what you just said it says. It doesn't say it's only indicated for implantation in the abdomen. It doesn't say that.
BY MR. SLATER:
Q. Doctor, you mentioned earlier, you were talking about --
A. And underneath there, it says contraindications, and it doesn't say that it should not be used in the vagina.
Q. Doctor, you talked earlier about the PROLIFT® and you spoke in the present tense, and you talked about use of GYNEMESH®®® PS.
You're aware that the PROLIFT® is no longer marketed, right?
MR. ISMAIL: Objection. Violates motion in limine and stipulation.
THE WITNESS: I'm aware of

Page 373

that, yes.
BY MR. SLATER:
Q. You made an effort to find out and the person you spoke to from Ethicon didn't know the answer, right?
MR. ISMAIL: Objection. Violation motion in limine and stipulation.
THE WITNESS: To find out?
BY MR. SLATER:
Q. Why Ethicon stopped selling the PROLIFT®?
A. Yes.
MR. ISMAIL: Objection. Also beyond the scope of redirect examination. And violates motions in limine.
BY MR. SLATER:
Q. And you made no further effort, so you don't know, even as you sit here now, why the PROLIFT® was withdrawn from the market, correct?
MR. ISMAIL: Same three objections.

Page 374

THE WITNESS: No.
BY MR. SLATER:
Q. And it wouldn't matter to you what the reason is, that wouldn't impact your opinions at all, right?
MR. ISMAIL: Same three objections. Beyond the scope. Violates court order and stipulation.
THE WITNESS: No.
BY MR. SLATER:
Q. Doctor, you were asked about whether or not there's documentation of complaints of dyspareunia after 2013.
Do you remember that?
A. Yes.
Q. Is there any doctor who is documenting that Ms. Hammons is -- no longer has dyspareunia? That it actually says that?
A. I don't remember any documentation of dyspareunia.
Q. Does any doctor, after 2013, say that Ms. Hammons does not have

Page 375

dyspareunia?
A. No.
Q. You talked about Dr. Heit saying that the mesh was improperly placed; counsel asked you about that a few minutes ago.
Do you recall that?
A. I do.
Q. Dr. Heit never said in the medical records, anywhere, not once, that the mesh was improperly placed, correct?
MR. ISMAIL: Objection.
THE WITNESS: Ask me that question again.
BY MR. SLATER:
Q. Dr. Heit does not write anywhere, in any medical record, that the mesh was improperly placed by Dr. Baker? It doesn't say that anywhere, does it?
A. Not in the medical record, no.
Q. It was only after this litigation got going and Dr. Heit was in a deposition that he said that for the

Page 376

first time, right?
A. That's correct.
Q. Are you aware of Dr. Heit's history of acting as a consultant for Ethicon and having been paid money by Ethicon over the years?
MR. ISMAIL: Objection. Beyond the scope. Lack of foundation. Assumes facts not in evidence.
THE WITNESS: No, I'm not.
BY MR. SLATER:
Q. You talked about Dr. Lackey and where -- remember counsel showed you a part of a medical record?
A. Yes.
Q. And you basically said, yeah, from that you could figure out it would be a bladder suspension or something like that, right?
A. Yes.
Q. But Dr. Lackey, in another record, calls it a TVT; so he wasn't able to figure that out, right?

Page 377

MR. ISMAIL: Objection. Compound. Lack of foundation.
THE WITNESS: Dr. Lackey, in a subsequent progress report, said that he could feel the tape and something about suspecting that it might be a TVT or something of that sort.
BY MR. SLATER:
Q. So from the records, he was not familiar with these mesh devices and didn't really know very much about them, right?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: That's one potential explanation. But as I was explaining, when you're asking somebody to recollect something, that's less reliable than their assessment at that time. So it could just be that he didn't remember what she told him.
I think when she presented

Page 378

it was three years later, wasn't it? Or two years later?
MR. SLATER: Move to strike from "but" forward.
BY MR. SLATER:
Q. Dr. Baker, if he had known all the risks of the PROLIFT®, as he said in his testimony he didn't, he could have referred Ms. Hammons to another doctor, right?
MR. ISMAIL: Objection. Calls for speculation.
THE WITNESS: Yes, he could have.
BY MR. SLATER:
Q. Dr. Baker could have referred Ms. Hammons to another doctor if she chose a procedure he didn't perform, correct?
MR. ISMAIL: Objection. Calls for speculation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. That happens all the time in

Page 379

the medical field, correct?
MR. ISMAIL: Objection. Lack of foundation.
THE WITNESS: Assuming that you have someone to refer to, yes.
BY MR. SLATER:
Q. You went through your calculations and peer review and all those things on your article.
Do you remember that?
A. Yes.
Q. Just to be clear, in the abstract, you talked about questionnaires and said based on the questionnaires you came to 24 percent, right?
A. I'd have to look at it again. We talked about the assessment --
Q. I'm asking you what you said in the abstract?
A. Possibly.
Q. In the article, you then decided, well, we don't want to do it that way, we're going to do it by the chart reviews and not consider the

Page 380

questionnaires, and that brought the number down 7 percent from what you had reported in the abstract, correct?
A. No.
Q. The number didn't go down by 7 percent?
A. No. I have explained that extensively what happened, why the abstract numbers are different than the final paper.
We weren't even done doing the study when we submitted the abstract. That's why the numbers are different.
Q. Does it say anywhere in the abstract that the method you're using to calculate the numbers is different than what was intended?
MR. ISMAIL: Objection. Vague. I don't even know what that means.
THE WITNESS: The methods that we used to calculate the numbers were not different than what was intended. But in my

Page 381

abstract -- where is it?
I state, All cases of PROLIFT® performed were evaluated. Patients were contacted by phone to assess sexual activity and obtain informed consent. Those that were sexually active were mailed a validated condition-specific questionnaires and a seven-items questionnaire. The rate of dyspareunia was calculated; type of dyspareunia, degree of dyspareunia, demographics, et cetera.
I say here that -- there's a part in here, I believe, where I explain the fact that there are several sexually active patients -- yes. So in the results, 128 PROLIFT® cases were performed during the study period. 68 were not sexually active. Of the remaining 60 sexually active patients, 11 had not yet resumed

Page 382

sexual intercourse but have enrolled in the study and will be evaluated over the next several months.

Indicating that this was not complete data.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. I only have a couple more questions.

A. Okay.

Q. This is conditional, in case the de Landsheere article is permitted, which we think is beyond the scope of the cross.

Doctor, in the de Landsheere article that you were asked about --

A. Yes.

Q. -- if you turn to Page E3.

A. Yes.

Q. They talk about the number of mesh exposures and 13 out of the 14 mesh exposures required surgery, correct?

A. Where are you reading that?

Page 383

Q. In the left column.

The most frequent complication was mesh exposure which happened --

A. What paragraph?

Q. -- in 14 cases.

A. Which one?

Q. Right in the middle of the column. Third paragraph.

A. Three patients had postop severe blood loss over 400, that paragraph?

Q. No, it's the next paragraph. Let me start over.

A. Okay.

Q. In the third paragraph, it starts with, A total of 19 patients required surgical intervention for mesh related complication.

A. Yes, 3.6 percent.

Q. And the most frequent complication was mesh exposure. There were 14 exposures. And then it says, 13 to 14 had to have surgery, partial mesh

Page 384

excision.

Right?

A. Right.

Q. And then further down, if you go through the complications, there were two patients with severe symptomatic mesh retraction, right?

A. Yes. Which was .4 percent of those patients.

MR. SLATER: Move to strike. Didn't ask that.

BY MR. SLATER:

Q. Doctor, you were asked questions about e-mails and whether that's scientific evidence.

Do you remember that?

A. Yes.

Q. Do you understand that in a court of law, company documents like e-mails and internal documents are admissible and can be considered by the jury in deciding whether the product was defective and whether Ethicon acted reasonably?

Page 385

MR. ISMAIL: Objection. Argumentative.

THE WITNESS: I accept that.

BY MR. SLATER:

Q. You didn't consider that information in forming your opinions, though, right?

A. Right.

MR. SLATER: Thank you very much.

- - -

EXAMINATION

- - -

BY MR. ISMAIL:

Q. Doctor, two questions.

On the de Landsheere paper --

MR. SLATER: I object to any further redirect.

MR. ISMAIL: Great. Then make it, and let me ask the question. Do you object?

MR. SLATER: You can do whatever you want.

MR. ISMAIL: Thank you.
MR. SLATER: Nobody jumped over the table.
BY MR. ISMAIL:
Q. Doctor, I want to go to the section that Mr. Slater just read to you about the de Landsheere paper.
A. Yes.
Q. He said two patients were reported here as having retraction, right?
A. Yes.
MR. SLATER: Objection. Foundation. Mischaracterizes. Hearsay.
BY MR. ISMAIL:
Q. The -- how many patients were in this study?
A. Over 500; 524.
Q. So what was the complication rate for the data that Mr. Slater directed you on recross-examination?
MR. SLATER: Same objections.

THE WITNESS: For the two patients it was .4 percent.
MR. ISMAIL: Thank you. Dr. Lowman, you're done.
VIDEO TECHNICIAN: This ends today's deposition. We're going off the record at 7:50 p.m.
- - -
(Whereupon, the deposition was concluded at 7:50 p.m.)
- - -

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

Amanda Maslynsky-Miller
Certified Realtime Reporter
Dated: December 13, 2015

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

LAWYER'S NOTES

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